Federal Unfair Competition: Lanham Act 43a
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Chapter 6. Advertising

References

§ 6:3. Right to prohibit false advertising

West's Key Number Digest

West's Key Number Digest, Trade Regulation 870

A.L.R. Library

A.L.R. Index, Trademarks, Tradenames and Unfair Trade Practices

Treatises and Practice Aids

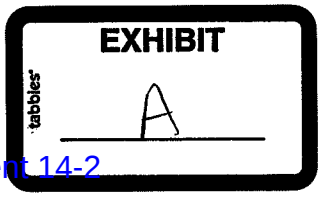
Lindey on Entertainment, Publishing and the Arts § 1:202 (2d ed.)

McCarthy on Trademarks and Unfair Competition §§ 27:34, 27:36, 27:37 (4th ed.)

In addition to creating a right to protect one's own advertising "look and feel" against copying, a competitor (or one likely to be injured) has the right, under Section 43(a), to seek an injunction and damages against false advertising directed to the inherent qualities[1] resident in defendant's goods or services.[2] Section 43(a), as amended in 1988, now recites that misrepresentation must be directed to the "nature, characteristics, qualities or geographical origin" of the goods or services.[3] An early Section 43(a) case directed to false advertising was unsuccessfully challenged by a motion to dismiss.[4]

Section 43(a) requires that alleged falsity be in commercial advertising and promotion.[5]

With respect to a complainant's entitlement or standing to assert a litigable claim of false advertising, practitioners should be mindful that two tests have emerged. A number of Circuits, such as the Second, Seventh, and Tenth, have determined that false advertising claims not involving the use of another's trademark are only actionable when brought by a wrongdoer's competitors,[5.10] whereas other Circuits have a "less categorical," multi-pronged test that focuses enforcement upon the protection of commercial interests and the prevention of competitive injury, viz., the nature of plaintiff's injury, especially in terms of whether the injury was a type that Congress sought to redress by providing a private remedy for violation of the anti-trust laws, the directness or indirectness of the asserted injury and the proximity or remoteness of the party to the alleged wrongdoing, the speculativeness of the claim for damages, and the risk of duplicative damages.[5.20]



With respect to a proponent's entitlement to relief for false advertising, the First, Second and Eleventh Circuits have required that literally false or misleading statements in advertising must be a material element of a purchaser's decision,[5.30] whereas the Fifth Circuit has opined that literally false statements are presumed to mislead purchasers, so that evidence on materiality need not be produced.[5.40]

The Sixth Circuit,[6] in articulating the policy consideration underlying a private litigant's resort to false advertising actions under Section 43(a), said:

> Congress, however, has enacted a statute that creates a cause of action in federal court for false advertising. Protecting consumers from false or misleading advertising, moreover, is an important goal of the statute and a laudable public policy to be served. Under our economic system, competitors have the greatest interest in stopping misleading advertising, and a private cause of action under section 43(a) allows those parties with the greatest interest in enforcement, and in many situations with the greatest resources to devote to a lawsuit to enforce the statute rigorously.[7]

The scope of Section 43(a) with respect to false advertising is much broader and more effective than the common law cases directed to false advertising.[8]

There are a myriad of judicial formulations used to express what is required to prove a Section 43(a) claim asserted against a defendant for relief from false advertising. Essentially, however, the following elements must be demonstrated: the defendant has made false statements of fact as to a product,[8.50] or its quality,[9] with such falsity flowing from actual misstatements, partially correct statements, or failures to disclose; there is actual deception or at least a tendency to deceive a substantial segment of the relevant audience; the deception must be material in that it is likely to influence purchasing decisions;[9.10] the advertised goods must be in, or affect, interstate commerce;[9.50] and there is a likelihood of injury, stemming either from a decline in sales or loss in good will.[10]

An unusual case of substantial interest to anyone engaged in significant advertising campaigns may be found in *Phoenix of Broward, Inc. v. McDonald's Corp.*[10.10] In that action, a Burger King franchisee, on behalf of itself and similarly situated franchisees, claimed that defendant had engaged in false advertising as a consequence of representing that all of its customers "had a fair and equal opportunity to win all of the offered prizes," including the million dollar grand prize. Despite the initiation of an investigation by the FBI, defendant continued to advertise and promote its games.

In 2001, the U.S. Department of Justice and the FBI made the announcement that various of defendant's promotional games "had been compromised by a criminal ring" within Simon Marketing, an independent contractor retained to operate the games. While forty-six individuals ultimately pled guilty to charges of conspiracy and mail fraud, the Attorney General of the United States had publicly stated that this fraudulent "scheme [had] denied McDonald's customers a fair and equal chance of winning." In a nutshell, it was the felonious conduct of multiple third parties that rendered defendant's advertising false.

In its assessment of the defendant's motion to dismiss, the court preliminarily observed that a party's good faith or lack of intent to deceive was not a defense to a literally or impliedly false advertising charge and that Section 43(a) had been recognized as creating a strict liability tort.[10.20] It then proceeded to grant the motion to dismiss on the ground that plaintiff lacked prudential standing to bring its claim, in light of the multiple factors relied upon by the Third and Fifth Circuits to determine standing under the antitrust laws:[10.30]

- the nature of plaintiff's injury;
- the directness or indirectness of the claimed injury;
- the proximity or remoteness of the party to the allegedly injurious conduct;
- the speculativeness of damages; and
- the risk of duplicative damages or the complexity of apportioning damages.

Applying the foregoing standard and recognizing that it was doubtful that Congress sought, by its enactment of the Lanham Act, "to redress advertising rendered false by the criminal conduct of third parties," the court disposed of the matter by ruling that plaintiff lacked the requisite standing to assert its claim.[10.31]

In yet another uncommon instance, a district court in Georgia preliminarily enjoined defendants from selling or offering for sale, or otherwise advertising or promoting, the sale of dietary supplement products containing ephedrine alkaloids which had been "removed without authorization or permission from [plaintiff's] business location, warehouse and storage facilities."[10.35]

In cases where the allegedly offending content of an advertise ment is literally true, but rather "implicitly" false or deceptive, a court's inquiry into the potentially misleading and deceptive character of an advertisement is to be effected not by its own subjective reaction to an advertisement and its presentation but rather to the reaction of the group to whom the advertisement is directed.[11] This does not mean, however, that the trial court is bound by the conclusions of market analysts and/or other expert witnesses. To be sure, a court's individual and subjective reaction to a given advertisement is not determinative although, as finder of fact, a court is "obliged to judge for itself whether the evidence of record establishes that others are likely to be misled or confused."[12] In any such analysis, one court observed that appropriate tribute should be given to "its own experience and understanding of human nature in drawing reasonable inferences about the reactions of consumers to the challenged advertising."[13]

Nevertheless, a party's failure to offer consumer surveys or other expert testimony, and/or documentary evidence, may be fatal to a claim that a particular advertisement or commercial is misleading or has a tendency to mislead.[14] On the other hand, testimony—whether expert or otherwise—regarding the "inherent quality" of a misrepresentation, as well as testimony relating to underlying consumer test results and methodologies, will invariably be considered in a determination of whether a violation of Section 43(a) exists.[15]

> Whether or not the statements made in the advertisements are literally true, § 43(a) of the Lanham Act encompasses more than blatant falsehoods. It embraces "innuendo, indirect intimations, and ambiguous suggestion" evidenced by the consuming public's misapprehension of the hard facts underlying an advertisement.
>
> We do not hold that every misrepresentation concerning consumer test results or methodology can result in liability pursuant to § 43(a). But where depictions of consumer test results or methodology are so significantly misleading that the reasonably intelligent consumer would be deceived about the product's inherent quality or characteristics, an action under § 43(a) may lie.[16]

Of particular significance in the Sassoon case[17] was the fact that the court specifically concluded that at least one statement, that nine hundred women (as opposed to teenagers), like the well-known fashion model Cristina Ferrare, tried defendant's shampoo whereas in point of fact only two thirds of the sample were adult women, made by Bristol-Myers in its advertising, appeared to be facially false on the record and was thus enjoined without regard to consumer reaction.[18]

In McNeilab, Inc. v. American Home Products Corp.,[19] plaintiff-manufacturer of "Extra Strength Tylenol" alleged inter alia that an advertisement claiming that defendant's Maximum Strength Anacin contained more "of the pain reliever that doctors recommend most" was deceptive because it failed to apprise the audience that the particular ingredient was aspirin, which has certain assertedly deleterious side effects and should not be used by all consumers. In rejecting that claim, the court observed that "a failure to inform consumers of something, even something they should know, is not *per se* a misrepresentation actionable under Section 43(a) of the Lanham Act."[20]

Other cases bearing on questions of falsity in advertising are Vidal Sassoon, Inc. v. Bristol-Myers Co.[21] (the intent and total effect of defendant's advertisements were found to lead consumers into erroneous belief that defen-

dant's product was competitively superior); R.J. Reynolds Tobacco Co. v. Loew's Theatres, Inc.[22] (bias in defendant's consumer test was found to cause deception as to the quality of defendant's goods); American Home Products Corp. v. Abbott Laboratories[23] (literal meaning of advertisement must be determined in light of context in which challenged statements are made and defendant's intent in making them); and Plough, Inc. v. Johnson & Johnson Baby Products Co.[24] (in light of context and defendant's intent, literal meaning of the word "sunscreen" was limited to products sought by consumers concerned with health hazards of sun exposure; therefore, defendant's advertising claiming its product was "Number One Of Selling Sunscreen" was not facially false).

Finally, bad faith or intent to deceive are not a necessary element in proving a false advertising or false representation case.[25] A complaint for false advertising need not be pleaded with particularity,[26] although there is emerging case law to the contrary.[27]

[FN1] Cashmere & Camel Hair Mfrs. Institute v. Saks Fifth Ave., 284 F.3d 302 (1st Cir. 2002) (presumption of consumer deception arises where a defendant has misrepresented a material fact relating to the inherent quality or characteristic of the article sold). The 1988 Amendments to Section 43(a) use the language "nature, characteristics [and] qualities."

[FN2] S.C. Johnson & Son, Inc. v. Clorox Co., 241 F.3d 232 (2d Cir. 2001) (permanent injunction against TV and print advertisement showing Zip Loc bag leaking water affirmed); Coastal Abstract Service, Inc. v. First American Title Ins. Co., 165 F.3d 658, 49 U.S.P.Q.2d (BNA) 1349 (9th Cir. 1998), see superseding opinion, 1999 WL 152594 (9th Cir. 1998) (false advertising judgment based on jury award relating to mortgage services reversed); Florida Breckenbridge, Inc. v. Solvay Pharmaceuticals, Inc., 47 U.S.P.Q.2d (BNA) 1491 (S.D. Fla. 1998) (falsity of advertising is usually a question of fact); Fuller Brothers v. International Marketing, 33 U.S.P.Q.2d (BNA) 1855 (D. Or. 1995) (where parties are not competitors—no recovery for false advertising); Appraisers Coalition v. Appraisal Institute, 845 F. Supp. 592 (N.D. Ill. 1994) (allegation of false advertising relates to quality of appraisal services and is therefore not dismissable); Media Arts Int'l Ltd. v. Trillium Health Prods., 25 U.S.P.Q.2d (BNA) 1764 (E.D. Pa. 1992) (those portions of TV commercial including false statements about plaintiff's juice appliance preliminarily enjoined); Grove Fresh Distributors Inc. v. New England Apple Products Co., 969 F.2d 552, 23 U.S.P.Q.2d (BNA) 1855 (7th Cir. 1992) (jury verdict rendered where representations, viz., that orange juice was "100% Florida" and carried the Florida Seal of Approval, were found actionable under Section 43(a)); Official Airline Guides, Inc. v. Churchfield Publications Inc., 756 F. Supp. 1393, 17 U.S.P.Q.2d (BNA) 1987 (D. Or. 1990) (plaintiff failed to prove that defendants disseminated advertising and promotional material containing false and misleading descriptions and misrepresentations of fact regarding, inter alia, circulation of publication and affiliation with third parties); Energy Four Inc. v. Dornui Medical Sys. Inc., 765 F. Supp. 724 (N.D. Ga. 1991) (false advertising in letter and brochure found relating to medical devices for treating kidneys preliminarily enjoined); Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 278, 213 U.S.P.Q. (BNA) 24, 28 (2d Cir. 1981); Sheldon Friedlich Marketing v. Carol Wright Sales, 219 U.S.P.Q. (BNA) 883 (S.D.N.Y. 1983) ("patent applied for" claim not related to inherent quality; no relief). *But see* Thompson Everett Inc. v. National Cable Advertising, L.P., 850 F. Supp. 470 (E.D. Va. 1994) (defendant's misrepresentations regarding plaintiff's status, as opposed to some aspect of a product or service, not actionable under § 43(a)).

[FN3] Wellness Pub. v. Barefoot, 2008-1 Trade Cas. (CCH) ¶76040, 2008 WL 108889 (D.N.J. 2008) (court granted a motion to dismiss a claim for false advertising since plaintiff's allegations failed to plead the claim with even a modified degree of the requisite particularity); Baden Sports, Inc. v. Molten, 541 F. Supp. 2d 1151, 2008-1 Trade Cas. (CCH) ¶76074 (W.D. Wash. 2008) (in its denial of defendants' motions for judgment as a matter of law and for a new trial, the court ruled that plaintiff's false advertising claim was not precluded by Dastar since the resolution of that question related to the nature, characteristics and qualities of the basketballs in suit and since the claim of "innovation" did not relate to the inventor of defendants' "dual cushion" technology); Parker v. Learn Skills Corp., 530 F. Supp. 2d 661, R.I.C.O. Bus. Disp. Guide (CCH) P 11472, 2008-1 Trade Cas. (CCH) ¶76107 (D. Del. 2008) (court dismissed plaintiff's

claim for false advertising since the complained of statements merely spoke "more to name calling and personal opinions regarding [the individual] plaintiff" rather than false or misleading statements regarding the parties' products); Antidote Intern. Films, Inc. v. Bloomsbury Pub., PLC, 467 F. Supp. 2d 394, 2007-1 Trade Cas. (CCH) P 75572 (S.D. N.Y. 2006) (court dismissed plaintiff's claim for false advertising since defendants' alleged misrepresentations regarding false authorship cannot, under Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23, 123 S. Ct. 2041, 66 U.S.P.Q.2d 1641, 194 A.L.R. Fed. 731 (2003), be construed as referring to the nature, characteristic or quality of defendants' goods); Tire Kingdom Inc. v. Morgan Tire & Auto Inc., 915 F. Supp. 360 (S.D. Fla. 1996) (alleged false advertising—not pertaining to nature, quality, characteristics, or geographic origin of defendant's products—found dismissable on summary judgment).

[FN4] Insignia Systems, Inc. v. News America Marketing In-Store, Inc., 2007-2 Trade Cas. (CCH) ¶75922, 2007 WL 2893374 (D. Minn. 2007) (court refused to dismiss a counterclaim for false advertising since plaintiff's alleged misrepresentations regarding the legality of defendants' conduct related to defendants' commercial activities, as well as the quality and value of the services they rendered); Klockner-Humboldt-Deutz v. Hewitt-Robbins, 205 U.S.P.Q. (BNA) 257 (D.S.C. 1978) (false advertising relating to cone crusher equipment held actionable); *see also* Testing Systems, Inc. v. Magnaflux Corp., 251 F. Supp. 286 (E.D. Pa. 1966) (statements that plaintiff's product was "only about 40% as effective" as defendant's, and that plaintiff's product was "no good" and was "thrown out" by the United States Government held on defendant's motion to dismiss to be actionable, the court finding, "It has even been said that he (a competitor) may boast untruthfully of his wares (citations omitted)); *but see* the Lanham Trademark Act, 15 U.S.C.A. § 1125(a), which gives a civil action to anyone injured or damaged by false advertising of goods involved in interstate commerce" (parentheses supplied).

[FN5] Cancer Genetics, Inc. v. Hartmayer, 2008-1 Trade Cas. (CCH) ¶76072, 2008 WL 323738 (D.N.J. 2008) (court denied plaintiff's application for a preliminary injunction and dismissed its Lanham Act claim since the individual defendant's alleged oral statement to a potential investor was not for the purpose of influencing the purchasing decisions of consumers and did not otherwise constitute advertising or promotion); Trans USA Products, Inc. v. Howard Berger Co., Inc., 2008 WL 852324 (D.N.J. 2008) (court granted a motion to dismiss a claim for false advertising since, among other things, the complaint lacked sufficient allegations that defendants were engaged in commercial advertising or promotion, or that they were engaged in interstate commerce); Futuristic Fences, Inc. v. Illusion Fence Corp., 558 F. Supp. 2d 1270 (S.D. Fla. 2008) (court, *sua sponte*, granted summary judgment to defendants since the cease and desist letters sent to plaintiff's actual and prospective distributors did not constitute commercial advertising or promotion); Cargill Inc. v. Progressive Dairy Solutions, Inc., 70 Fed. R. Serv. 3d 957 (E.D. Cal. 2008) (court awarded summary judgment to plaintiffs on defendants' counterclaim for false advertising since the alleged misrepresentations were published within the "litigation privilege" and were not, in any event, sufficiently disseminated so as to comprise advertising and promotion); Midwest Canvas Corp. v. Commonwealth Canvas, Inc., 2008 WL 162757 (N.D. Ill. 2008) (court granted a motion to dismiss a false advertising claim, under Twombly, since the allegedly false statements appearing on an invoice and "work order" could "hardly be construed to have been disseminated sufficiently to the relevant purchasing public because it lacked the element of publicity ..." and since it [was] not an inducement to buy ..."); White Mule Co. v. ATC Leasing Co. LLC, 540 F. Supp. 2d 869, 2008-2 Trade Cas. (CCH) ¶76239 (N.D. Ohio 2008) (court dismissed Lanham Act claims in their entirety since the communications regarding plaintiff's alleged patent infringement and the court's issuance of a temporary restraining order, while perhaps comprising commercial speech, were of extremely limited circulation, were not directed to influence consumers and, therefore, did not comprise advertising or promotion); Chamilia, LLC v. Pandora Jewelry, LLC, 85 U.S.P.Q.2d 1169, 2007-2 Trade Cas. (CCH) ¶75945, 2007 WL 2781246 (S.D. N.Y. 2007) (court granted summary judgment to defendant since its transmission of approximately four-hundred letters was principally directed to retailers with whom it had exclusive sales agreements and was, therefore, not "part of an organized campaign to penetrate the jewelry market"); MIZ Engineering, Ltd. v. Avganim, 2007-2 Trade Cas. (CCH) ¶75946,

2007 WL 2892623 (E.D. Va. 2007) (court denied third-party defendants' motion to dismiss since the letter writing and telephone campaign undertaken by them facially comprised commercial advertising); Brooks ex rel. Estate of Bell v. The Topps Co., Inc., 2007 WL 4547585 (S.D. N.Y. 2007) (court granted summary judgment to defendant-publisher of baseball cards on plaintiff's false advertising claim since a "nickname statement," in this case about the source of plaintiff's father's name "Cool Papa," was not commercial speech and, therefore, did not constitute advertising or promotion); Junction Solutions, LLC v. MBS Dev, Inc., 2007 WL 4234091 (N.D. Ill. 2007) (the filing of a lawsuit against a competitor, even if filed maliciously and based on false statements, is not a violation of the Lanham Act since the statute does not extend to *all* communications made by one competitor against another, but only to those made in commercial advertising or promotion); ConsulNet Computing, Inc. v. Moore, 84 U.S.P.Q.2d 1640, 2007-2 Trade Cas. (CCH) ¶75892, 2007 WL 2702446 (E.D. Pa. 2007) (on a grant of summary judgment to plaintiff, the court ruled that an allegedly disparaging statement was not actionable since it did not comprise "advertising or promotion"); Zinus Inc. v. Simmons Bedding Co., 2007 WL 4287391 (N.D. Cal. 2007), reconsideration granted, 2008 WL 162531 (N.D. Cal. 2008) (court provisionally granted a motion to dismiss and ruled that a cease and desist letter, sent by defendants' counsel and comprising commercial speech made by a competitor, had not been alleged to have been sufficiently dissiminated or have influenced purchasing decisions, so as to comprise advertising or promotion); M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc., 2007 WL 979854 (D.N.J. 2007) (defendants-counterclaimants' transmission of letters to plaintiff and its customers, and charging them with patent infringement or contributory patent infringement, was ruled, on summary judgment, to be non-actionable since the letters did not comprise commercial advertising or promotion); Kinderstart.com LLC v. Google, Inc., 2007-1 Trade Cas. (CCH) P 75643, 2007 WL 831806 (N.D. Cal. 2007) (court granted defendant's motion to dismiss a claim for false advertising since defendant's alleged manipulation of its allegedly objective search results did not constitute advertising or promotion); Imig, Inc. v. Electrolux Home Care Products, Ltd., 2007-1 Trade Cas. (CCH) P 75688, 2007 WL 900310 (E.D. N.Y. 2007) (court granted defendant's motion for summary judgment on plaintiff's false advertising claim since there was no evidence that the statements had actually been made); Caldon, Inc. v. Advanced Measurement & Analysis Group, Inc., 2007-1 Trade Cas. (CCH) P 75758, 2007 WL 1656257 (W.D. Pa. 2007) (false advertising under the Lanham Act embraces more than "traditional" advertising and includes, for example, misrepresentations and disparaging statements made in submissions to a regulatory agency, in this case the Nuclear Regulatory Commission, and disseminated to customers and potential customers); Carter v. ALK Holdings, Inc., 510 F. Supp.2d 1299 (N.D. Ga. 2007) (court dismissed plaintiff's claim for false advertising since the listing of defendant as a co-inventor in a patent application did not constitute commercial advertising or promotion); Conditioned Ocular Enhancement, Inc. v. Bonaventura, 458 F. Supp. 2d 704 (N.D. Ill. 2006) (on plaintiffs' motion to dismiss counterclaims, the court ruled that patentee-plaintiffs' transmission of cease and desist letters sent to defendants' current customers did not constitute commercial advertising or promotion in violation of the Lanham Act and were not sent in bad faith); Croton Watch Co., Inc. v. National Jeweler Magazine, Inc., 2006-2 Trade Cas. (CCH) P 75402, 2006 WL 2254818 (S.D. N.Y. 2006) (court dismissed action for failure to state a claim for false advertising since the article appearing in a trade publication was not deemed to be advertising or promotion, but rather was free, non-commercial speech protected by the First Amendment); Land's End, Inc. v. Remy, 447 F. Supp. 2d 941 (W.D. Wis. 2006) (defendants were granted summary judgment on plaintiff's false advertising claim since they made no statements to consumers in furtherance of the "typosquatting" scheme and since their surreptitious conduct was the last thing that could be considered advertising); Storage Technology Corp. v. Custom Hardware Engineering & Consulting, Ltd., 2006 WL 1766434 (D. Mass. 2006) (on summary judgment, court rules that the transmission of five e-mails, comprising statements of opinion by a sales representative to a customer, do not comprise commercial advertising or promotion disseminated to a relevant purchasing public); New.Net, Inc. v. Lavasoft, 356 F. Supp. 2d 1090 (C.D. Cal. 2004) (Lanham Act claim was dismissed since the accused statement could not be regarded as commercial in character); Sanitec Industries, Inc. v. Micro-Waste Corp, 2006 WL 1544529 (S.D. Tex. 2006) (counterclaims dismissed on plaintiff's motion for summary judgment since plaintiff's transmission of the instant action's complaint to a third-party hospital did not encompass advertising, but even if it did, defendant failed to identify any allegations in the complaint that were objectively false, misleading or, for that matter, deceptive and failed to show any

injury), *see* related opinion, Sanitec Industries, Inc. v. Micro-Waste Corp., 2006 WL 3455000 (S.D. Tex. 2006) (court entered judgment against plaintiff and dismissed the complaint since, among other things, plaintiff failed to sustain its burden of establishing a likelihood of confusion or injury, and further failed to establish that any alleged misrepresentation influenced purchasing decisions); Tercica, Inc. v. Insmed Inc., 2006-2 Trade Cas. (CCH) P 75362, 2006 WL 1626930 (N.D. Cal. 2006) (allegedly false and misleading communications to actual and prospective investors do not constitute advertising or promotion to a relevant class of consumers); Sigma Dynamics, Inc. v. E. Piphany, Inc., 2004 WL 2648370 (N.D. Cal. 2004) (statements made to primarily influence investors were not cognizable under the Lanham Act); Chicago Consulting Actuaries, LLC v. Scrol, 2005-1 Trade Cas. (CCH) P 74811, 2005 WL 819555 (N.D. Ill. 2005) (isolated oral statements by sales persons do not amount to commercial advertising or promotion); John Wiley & Sons, Inc. v. Palisade Corp., 2005-2 Trade Cas. (CCH) P 75029, 2005 WL 2739267 (S.D. N.Y. 2005) (plaintiff not entitled to injunction on its pertinent false advertising claim since no evidence was proffered that defendant's "isolated misstatement" was likely to recur); Unique Sports Generation, Inc. v. LGH-III, LLC, 2005 WL 2414452 (S.D. N.Y. 2005) (in an action commenced by the owner, an NBA licenseee, of the mark "Unique" for sportswear against defendant's use of the allegedly phonetically similar marks "OUNK" and "UNK" for competitive products, court granted defendant leave to assert additional counterclaims since plaintiff's statement, made in the course of a national trade show, that defendant's products were "fakes," was a representation of fact and suggested the type of "widespread dissemination" actionable under the Lanham Act's proscription of false advertising); Agency Development, Inc. v. Medamerica Ins. Co. of New York, 142 Fed. Appx. 545, 2005-2 Trade Cas. (CCH) P 74936 (2d Cir. 2005) (2d Cir. 2005) (court affirms denial of plaintiff's motion to add a claim for false advertising since annual reports were not commercial speech and since alleged misrepresentations were not, in any event, material); Optimum Technologies, Inc. v. Home Depot USA, Inc., 2006-1 Trade Cas. (CCH) P 75104, 2005 WL 3307508 (N.D. Ga. 2005) (isolated comments made by sales personnel and product placement insignia do not constitute "commercial advertising or promotion" so that false advertising claim is dismissed on motion for partial summary judgment), aff'd, 2007 WL 465535 (11th Cir. 2007) (trial court's grant of summary judgment to defendants on plaintiff's claim for monetary damages was upheld), *see* related opinion, Optimum Technologies, Inc. v. Henkel Consumer Adhesives, Inc., 2006 WL 1663357 (N.D. Ga. 2006), order aff'd, 496 F.3d 1231, 83 U.S.P.Q.2d 1769 (11th Cir. 2007) (court granted partial summary judgment to defendants on certain Lanham Act claims and judgment as a matter of law on another Lanham Act claim), aff'd, 2007 WL 2377455 (11th Cir. 2007); Clark Consulting, Inc. v. Financial Solutions Partners, LLC, 2005 WL 3097892 (S.D. N.Y. 2005) (while a party's omissions are not actionable under the Lanham Act since the Act imposes no affirmative duty of disclosure, court denies motion to dismiss counterclaim since its allegations extended to misrepresentations to customers and potential customers and were, therefore, made in the context of "commercial advertising or promotion"); Schwarz Pharma, Inc. v. Breckenridge Pharmaceutical, Inc., 388 F. Supp. 2d 967, 2005-2 Trade Cas. (CCH) P 75038 (E.D. Wis. 2005) (summary judgment granted, dismissing counterclaim, since a single oral statement to a pharmacist does not constitute "commercial advertising or promotion"); Gilson v. Rainin Instrument, LLC, 2005 WL 955251 (W.D. Wis. 2005) (on summary judgment, court finds that accused, including oral, misrepresentations "in the form of a person-to-person pitch," do not constitute "commercial advertising or promotion" within the meaning of the Lanham Act), see related opinion, Gilson v. Rainin Instrument, LLC, 2005 WL 1899471 (W.D. Wis. 2005) (defendant's renewed motion for judgment on breach of contract claim denied); Z-Tel Communications, Inc. v. SBC Communications, Inc., 331 F. Supp. 2d 513, R.I.C.O. Bus. Disp. Guide (CCH) P 10741, 2004-2 Trade Cas. (CCH) P 74534 (E.D. Tex. 2004) (allegations of false billing practices, not to mention advertising that proclaimed plaintiff was a "parasite" who (sic) gave nothing back to consumers, constitute misrepresentations of fact in commercial advertising or promotion and survive motion to dismiss); Professional Sound Services, Inc. v. Guzzi, 349 F. Supp. 2d 722, 77 U.S.P.Q.2d (BNA) 1375 (S.D. N.Y. 2004), aff'd, 159 Fed. Appx. 270 (2d Cir. 2005) (defendant's oral disparaging statement that plaintiff lies to its customers about consignment sales it transacted not actionable, on summary judgment, since comment was not used in "advertising or promotion"); First Health Group Corp. v. BCE Emergis Corp., 269 F.3d 800, 60 U.S.P.Q.2d (BNA) 1532 (7th Cir. 2001) (summary judgment affirmed where representations made in contract negotiations or included in contract language are not encompassed in "commercial advertising or pro-

motion" language in Section 43(a)(1)(B)); Section 43(a)(1)(B); see Sports Unlimited, Inc. v. Lankford Enterprises, Inc., 275 F.3d 996, 61 U.S.P.Q.2d (BNA) 1260 (10th Cir. 2002) (minimal distribution of reference list containing adverse material was held not to be commercial advertising or promotion to support false adversity claim).

[FN5.10] *See, e.g.*, Telecom Intern. America, Ltd. v. AT & T Corp., 280 F.3d 175, 2001-2 Trade Cas. (CCH) P 73490 (2d Cir. 2001); L.S. Heath & Son, Inc. v. AT & T Information Systems, Inc., 9 F.3d 561, 28 U.S.P.Q.2d 1659, 1993-2 Trade Cas. (CCH) P 70468, 22 U.C.C. Rep. Serv. 2d 27 (7th Cir. 1993), as amended on denial of reh'g, (Dec. 8, 1993) and Stanfield v. Osborne Industries, Inc., 52 F.3d 867, 34 U.S.P.Q.2d 1456 (10th Cir. 1995).

[FN5.20] *See, e.g.*, Conte Bros. Automotive, Inc. v. Quaker State-Slick 50, Inc., 165 F.3d 221, 49 U.S.P.Q.2d 1321, 1999-1 Trade Cas. (CCH) P 72383 (3d Cir. 1998) and Procter & Gamble Co. v. Amway Corp., 242 F.3d 539, 29 Media L. Rep. (BNA) 1449, 58 U.S.P.Q.2d 1008, R.I.C.O. Bus. Disp. Guide (CCH) P 10020, 2001-1 Trade Cas. (CCH) P 73161 (5th Cir. 2001).

[FN5.30] *See, e.g.*, HipSaver Co., Inc. v. J.T. Posey Co., 490 F. Supp. 2d 55, 2007-1 Trade Cas. (CCH) P 75742 (D. Mass. 2007) (even where an advertisement has been shown to be literally false or made with an intent to deceive, it must be shown that the misrepresentation was material and had an influence on purchasing decisions) and later opinion, HipSaver Co., Inc. v. J.T. Posey Co., 497 F. Supp. 2d 96, 2007-2 Trade Cas. (CCH) ¶75851 (D. Mass. 2007) (while the court imposed sanctions upon plaintiff for its failures in the course of discovery, it permitted plaintiff to submit a proffer of evidence regarding advertising injury and causation and its theory of damages); Swatch S.A. v. New City, Inc., 454 F. Supp. 2d 1245 (S.D. Fla. 2006) (plaintiffs' previous acceptance of unendorsed warranty certificates does not shield defendant from liability for trademark infringement, but issue of fact existed as to whether the presence or absence of a warranty made a material difference to a consumer purchasing decision); Cashmere & Camel Hair Mfrs. Institute v. Saks Fifth Ave., 284 F.3d 302, 2002-1 Trade Cas. (CCH) P 73628 (1st Cir. 2002); S.C. Johnson & Son, Inc. v. Clorox Co., 241 F.3d 232, 57 U.S.P.Q.2d 1912, 2001-1 Trade Cas. (CCH) P 73231 (2d Cir. 2001) and Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 2002-2 Trade Cas. (CCH) P 73809 (11th Cir. 2002). *See also* Optivus Technology, Inc. v. Ion Beam Applications S.A., 469 F.3d 978, 80 U.S.P.Q.2d 1839 (Fed. Cir. 2006) (trial court's grant of summary judgment to defendant on plaintiffs' Lanham Act claim was reversed, the court ruling that a question of fact existed as to whether defendant's representations made in a financing statement were materially false).

[FN5.40] Pizza Hut, Inc. v. Papa John's Intern., Inc., 227 F.3d 489, 56 U.S.P.Q.2d 1246, 2000-2 Trade Cas. (CCH) P 73029 (5th Cir. 2000). *See also* Outdoor Technologies, Inc. v. Vinyl Visions, LLC, 2006 WL 2849782 (S.D. Ohio 2006) (actual consumer deception is presumed to flow from a literally false statement in advertising).

[FN6] Coca-Cola Co. v. Procter & Gamble Co., 822 F.2d 28, 3 U.S.P.Q.2d (BNA) 1364 (6th Cir. 1987) (allegation that "Citrus Hill" orange juice was made from the "heart of the orange" states a claim for relief).

[FN7] Coca-Cola Co. v. Procter & Gamble Co., 822 F.2d 28, 31, 3 U.S.P.Q.2d (BNA) 1364, 1367 (6th Cir. 1987); W.L. Gore & Associates, Inc. v. Totes Inc., 788 F. Supp. 800, 23 U.S.P.Q.2d (BNA) 1091 (D. Del. 1992) (false advertising is contrary to the public interest since the public has a right to information which will permit them to assess the quality of a product and the acceptability of its price, and since the public has an interest in commercial competition and resulting technological innovation).

[FN8] H.W. Carter & Sons Inc. v. William Carter Co., 913 F. Supp. 796, (S.D.N.Y. 1996) (misstatements appearing in defendant's letter to the trade were not sufficiently material to rise to the level of a Section

43(a) violation); Ortho Diagnostic Systems Inc. v. Abbott Labs. Inc., 920 F. Supp. 455 (S.D.N.Y. 1996) (to be actionable, allegedly false or misleading representations must be material to a purchaser's decision); *see, e.g.,* Smith-Victor Corp. v. Sylvania Elec. Products, Inc., 242 F. Supp. 302, 146 U.S.P.Q. (BNA) 701 (N.D. Ill. 1965) (specific advertising claims involving home picture light not dismissable). The court said: "The scope of Section 43(a) is much broader than the common law of false advertising."

[FN8.50] Alphamed Pharmaceuticals Corp. v. Arriva Pharmaceuticals, Inc., 2005 WL 357326 (S.D. Fla. 2005) (plaintiff lacked standing to sue for false advertising since allegedly false advertisements did not refer to specific goods or services). *See also* Phoenix of Broward, Inc. v. McDonald's Corp., 441 F. Supp. 2d 1241, 2006-2 Trade Cas. (CCH) P 75401 (N.D. Ga. 2006) (while the court dismissed a franchisee's claim for false advertising on the ground that it lacked prudential standing, the court acknowledged that it was unaware of any authority supporting a violation, where the advertising became false or misleading because of the felonious conduct of third parties).

[FN9] OPA (Overseas Pub. Ass'n) Amsterdam BV v. American Institute of Physics, 973 F. Supp. 414 (S.D.N.Y. 1997) (where defendant's ad claims that its product is superior, plaintiff must affirmatively prove defendant's product equal or inferior).

[FN9.10] Midwest Canvas Corp. v. Commonwealth Canvas, Inc., 2008 WL 162757 (N.D. Ill. 2008) (a listing of manufacturers' construction materials, including those of the parties, was utilized by the NYDOT as a means of assuring quality control and public safety, and was thus informational and not an inducement to purchase any particular manufacturer's products); Benefit Resource, Inc. v. Apprize Technology Solutions, Inc., 2008 WL 2080977 (D. Minn. 2008) (court refused to issue a preliminary injunction since defendant's alleged misrepresentations, even if they were false or misleading, were not material in terms of influencing purchasing decisions).

[FN9.50] Unique Sports Products, Inc. v. Wilson Sporting Goods Co., 2007 WL 764411 (N.D. Ga. 2007) (in an action seeking relief from defendant's unauthorized depiction of Pete Sampras, the court granted defendant's motion for summary judgment on plaintiff's false advertising claim since the use of his picture alone was not literally false and since plaintiff failed to adduce evidence establishing deception, i.e., that use of the photograph was true, but nonetheless misleading); Static Control Components, Inc. v. Lexmark Intern., Inc., 487 F. Supp. 2d 861, 2007-2 Trade Cas. (CCH) P 75773 (E.D. Ky. 2007) (court denied declaratory judgment defendants' motion for summary judgment since an issue of fact existed as to whether various statements caused actual deception); Pestube Systems, Inc. v. HomeTeam Pest Defense, LLC, 2007 WL 973964 (D. Ariz. 2007) (to prevail on a false advertising claim, a proponent must establish that a statement is literally false or false by necessary implication, or that it was literally true, but likely to confuse or mislead relevant consumers); Edina Realty, Inc. v. TheMLSonline.com, 2006 WL 737064 (D. Minn. 2006) (on summary judgment, defendant's purchase of multiple search terms incorporating plaintiff's trademark and its use of hidden links and text on its website found to constitute a use in commerce since defendant purchased such terms to "generate its sponsored link advertisement"), *see* later opinion, Edina Realty, Inc. v. TheMSLOnline.com, 2006 WL 1314303 (D. Minn. 2006) (motion for reconsideration was denied).

[FN10] Republic Tobacco L.P. v. North Atlantic Trading Co., 2007-1 Trade Cas. (CCH) ¶75745, 2007 WL 1424093 (N.D. Ill. 2007) (summary judgment was awarded to defendants since various claims made in a promotional bulletin entitled "Cigarette Paper Review" were not literally false and since, in any event, plaintiff failed to establish that the statements created any consumer deception or resulted in injury to it), aff'd in part, 481 F.3d 442, 67 Fed. R. Serv. 3d 776 (7th Cir. 2007) (award of certain costs upheld), *see* related opinion, Republic Tobacco, L.P. v. North Atlantic Trading Co., Inc., 2007 WL 899030 (N.D. Ill. 2007) (court denied defendants' motion to join additional parties as plaintiffs since, among other things, complete relief was available without joinder). Iridex Corp. v. Synergetics, Inc., 2007 WL 781254 (E.D.

Mo. 2007) (court awarded summary judgment to plaintiff on defendant's Lanham Act counterclaim since defendant failed to establish an essential element of its false advertising claim, *viz.*, that plaintiff's statements to the FDA and defendant's customers were false and that such statements caused any damage to its goodwill); Republic Tobacco L.P. v. North Atlantic Trading Co., 2007-1 Trade Cas. (CCH) P 75745, 2007 WL 1424093 (N.D. Ill. 2007) (summary judgment was awarded to defendants since various claims made in a promotional bulletin entitled "Cigarette Paper Review" were not literally false and since, in any event, plaintiff failed to establish that the statements created any consumer deception or resulted in injury to it), see related opinion, Republic Tobacco, L.P. v. North Atlantic Trading Co., Inc., 2007 WL 899030 (N.D. Ill. 2007) (court denied defendants' motion to join additional parties as plaintiffs since, among other things, complete relief was available without joinder); Harvey Barnett, Inc. v. Shidler, 338 F.3d 1125, 67 U.S.P.Q.2d 1641 (10th Cir. 2003) (court affirmed the lower court's grant of summary judgment to defendants on plaintiff's claim for false advertising since it failed to establish a likelihood of confusion or the existence of any competitive injury); *see* later opinions, Harvey Barnett, Inc. v. Shidler, 200 Fed. Appx. 734 (10th Cir. 2006) (court, among other things, affirmed the jury's verdict against an individual defendant and the court's award of attorney's fees to another defendant, but only to the extent of non-Lanham Act claims) and Infant Swimming Research, Inc. v. Shidler, 2007 WL 601975 (D. Colo. 2007) (court awarded a reduction of attorneys' fees based upon plaintiff's over-all level of success and the nature and extent of the relief granted, not including the fees incurred in connection with the prosecution of its Lanham Act claims, and various defendants were directed to proportionally satisfy that obligation); Holmes Group, Inc. v. RPS Products, Inc., 424 F. Supp. 2d 271, 2006-1 Trade Cas. (CCH) P 75225 (D. Mass. 2006) (on summary judgment to defendant, court rules that plaintiff's claim for money damages would not lie since there was no evidence of actual lost sales or harm to plaintiff's goodwill); Berg v. Symons, 393 F. Supp. 2d 525, 2005-2 Trade Cas. (CCH) P 75039 (S.D. Tex. 2005) (false advertising claim fails in the absence of evidence that consumers were misled or deceived, or that plaintiff's ex-wife's transmission of letter caused any diversion of trade or actual economic injury); Cashmere & Camel Hair Mfrs. Institute v. Saks Fifth Ave., 284 F.3d 302 (1st Cir. 2002) (evidence of cost differential between fabrics in suit, as well as anecdotal statements from prospective consumers, may be used as evidence of harm or injury); Pizza Hut, Inc. v. Papa John's Intern., Inc., 227 F.3d 489, 56 U.S.P.Q.2d (BNA) 1246 (5th Cir. 2000) (failure to prove the existence of each of the five elements of false advertising is fatal to claim); Clorox Co. Puerto Rico v. Proctor & Gamble Commercial Co., 228 F.3d 24, 56 U.S.P.Q.2d (BNA) 1385 (1st Cir. 2000) (court adopts six elements required to be proved with respect to false advertising claims); US West, Inc. v. Business Discount Plan, Inc., 196 F.R.D. 576 (D. Colo. 2000) (to be actionable, false advertising claim must assert existence of competitive injury); Warner-Lambert Co. v. BreathAssure, Inc., 204 F.3d 87, 53 U.S.P.Q.2d (BNA) 1727 (3d Cir. 2000) (to prevail on claim for "false or misleading representation of a product," plaintiff must demonstrate, inter alia, a more than merely subjective belief that there is likelihood of injury in terms of declining sales or loss of goodwill); Surdyk's Liquor, Inc. v. MGM Liquor Stores, Inc., 83 F. Supp. 2d 1016 (D. Minn. 2000) (court lists five "standard" elements to be demonstrated in order to prevail on claim of false advertising); National Basketball Ass'n v. Motorola Inc., 105 F.3d 841, 41 U.S.P.Q.2d (BNA) 1585 (2d Cir. 1997) (in addition to establishing falsity of accused advertisement, plaintiff must also demonstrate that defendant's misrepresentation is material); Goldsmith v. Polygram Diversified Ventures, Inc., 37 U.S.P.Q.2d (BNA) 1321 (S.D.N.Y. 1995) (single letter from attorney to book publisher does not constitute "advertising or promotion" within ambit of Section 43(a) and complaint is, accordingly, dismissed); Buehler AG v. Ocrim SpA, 836 F. Supp. 1291, 29 U.S.P.Q.2d (BNA) 1001 (N.D. Tex. 1993) (claim under § 43(a) requires that commercial advertising or promotion materially misrepresent or misdescribe adversary's product *and* that such representation or description be false or verifiably misleading); Gordon & Breach Science Publishers S.A. v. American Inst. of Physics, 859 F. Supp. 1521, 32 U.S.P.Q.2d (BNA) 1705 (S.D.N.Y. 1994) (distribution of preprints of articles at librarians' conference is commercial speech within scope of § 43(a)), *see* later opinions, 905 F. Supp. 169, 37 USPQ2d 1289 (S.D.N.Y. 1995), 166 F.3d 438, 49 USPQ2d 1639 (2d Cir. 1999); Appraisers Coalition v. Appraisal Institute, 845 F. Supp. 592 (N.D. Ill. 1994) (allegation of false advertising not dismissable as mere puffery); Criticare Sys. Inc. v. Nellor Inc., 856 F. Supp. 495 (E.D. Wis. 1994) (whether defendant's display of doctor's letter concerning plaintiff's medical equipment was violation not an issue to be decided on summary judgment); BIEC Int'l, Inc. v.

Global Steel Services, Ltd., 791 F. Supp. 489 (E.D. Pa. 1992) (for an action to lie under Section 43(a), advertising materials, such as press releases and letters, must contain false and misleading statements, must deceive or tend to deceive a substantial portion of defendant's contacts, must be material (i.e., likely to influence purchasing decision), must travel in interstate commerce, and must result in likelihood of injury to plaintiff); Ragold, Inc. v. Ferrero, U.S.A., Inc., 506 F. Supp. 117, 124, 209 U.S.P.Q. (BNA) 835, 841 (N.D. Ill. 1980), citing Skil Corp. v. Rockwell Int'l Corp., 375 F. Supp. 777, 783, 183 U.S.P.Q. (BNA) 157, 160 (N.D. Ill. 1974), and Bernard Food Indus., Inc. v. Dietene Co., 415 F.2d 1279, 1283, 163 U.S.P.Q. (BNA) 264, 267 (7th Cir. 1969); *see also* Metro Mobile Cts. Inc. v. Newvector Communications, 643 F. Supp. 1289 (D. Ariz.) (false advertising in cellular phone business preliminarily enjoined), rev'd without op., 803 F.2d 724 (9th Cir. 1986); U-Haul Int'l Inc. v. Jartran Inc., 522 F. Supp. 1238, 212 U.S.P.Q. (BNA) 49 (D. Ariz. 1981), aff'd, 681 F.2d 1159, 216 U.S.P.Q. (BNA) 1077 (9th Cir. 1982) (false advertising found in promoting trailer and truck rental business).

[FN10.10] Phoenix of Broward, Inc. v. McDonald's Corp., 441 F. Supp. 2d 1241, 2006-2 Trade Cas. (CCH) P 75401 (N.D. Ga. 2006) (court granted motion to dismiss).

[FN10.20] Software AG, Inc. v. Consist Software Solutions, Inc., 2008-1 Trade Cas. (CCH) ¶76089, 2008 WL 563449 (S.D. N.Y. 2008) (defendants' extraterritorial and literally false statements were enjoined despite defendants' arguably good faith belief or opinion that such representations were truthful); Vector Products, Inc. v. Hartford Fire Ins. Co., 397 F.3d 1316 (11th Cir. 2005) and BeVier, "Competitor Suits for False Advertising Under Section 43(a) of the Lanham Act: A Puzzle in the Law of Deception," 78 Va. L. Rev. 40-41 (1992). In one of the most egregious counterfeiting schemes considered by the courts, the court granted plaintiffs' unopposed motion for summary judgment and held, in relevant part, that: "[s]ince a seller bears strict liability for violations of the Lanham Act, even an 'innocent' individual who sells goods bearing an infringing mark is liable for trademark infringement—intent is not required," Cartier Intern. B.V. v. Ben-Menachem, 2008 WL 64005 (S.D. N.Y. 2008) (court granted plaintiffs' motion for summary judgment) and cases cited therein.

[FN10.30] Conte Bros. Automotive, Inc. v. Quaker State-Slick 50, Inc., 165 F.3d 221, 49 U.S.P.Q.2d 1321, 1999-1 Trade Cas. (CCH) P 72383 (3d Cir. 1998) and Procter & Gamble Co. v. Amway Corp., 242 F.3d 539, 29 Media L. Rep. (BNA) 1449, 58 U.S.P.Q.2d 1008, R.I.C.O. Bus. Disp. Guide (CCH) P 10020, 2001-1 Trade Cas. (CCH) P 73161 (5th Cir. 2001). By way of contrast, the court referred to, but did not adopt, the more "categorical" teaching of the Seventh, Ninth and Tenth Circuits, viz., that standing to assert a false advertising claim was premised upon the proponent being a competitor which alleged that it had suffered a competitive injury, L.S. Heath & Son, Inc. v. AT & T Information Systems, Inc., 9 F.3d 561, 28 U.S.P.Q.2d 1659, 1993-2 Trade Cas. (CCH) P 70468, 22 U.C.C. Rep. Serv. 2d 27 (7th Cir. 1993), as amended on denial of reh'g, (Dec. 8, 1993); Waits v. Frito-Lay, Inc., 978 F.2d 1093 (9th Cir. 1992) (rejected by, Conte Bros. Automotive, Inc. v. Quaker State-Slick 50, Inc., 165 F.3d 221, 49 U.S.P.Q.2d 1321, 1999-1 Trade Cas. (CCH) P 72383 (3d Cir. 1998)); and Stanfield v. Osborne Industries, Inc., 52 F.3d 867, 34 U.S.P.Q.2d 1456 (10th Cir. 1995).

[FN10.31] The District Court's opinion in Phoenix of Broward, Inc. v. McDonald's Corp., 441 F. Supp. 2d 1241, 2006-2 Trade Cas. (CCH) P 75401 (N.D. Ga. 2006), aff'd, 489 F.3d 1156, 2007-1 Trade Cas. (CCH) P 75751 (11th Cir. 2007) (court held that plaintiff lacked prudential, but not constitutional, standing to bring an action for false advertising under Section 43(a) of the Lanham Act and adopted the reasoning of the Third Circuit in Conte Bros. Automotive, Inc. v. Quaker State-Slick 50, Inc., 165 F.3d 221, 49 U.S.P.Q.2d 1321, 1999-1 Trade Cas. (CCH) P 72383 (3d Cir. 1998).

[FN10.35] Hi-Tech Pharmaceuticals, Inc. v. Brand New Energy, Inc., 2008 WL 660292 (N.D. Ga. 2008); Atlas Copco AB v. Atlascopcoiran.com, 533 F. Supp. 2d 610 (E.D. Va. 2008) (based upon plaintiffs' filing of a verified complaint against multiple domain name registrations, the court granted their unopposed mo-

tion for summary judgment and ruled that defendants-domain names were used with a bad faith intent to profit from the goodwill symbolized by plaintiffs' mark).

[FN11] Cashmere & Camel Hair Mfrs. Institute v. Saks Fifth Ave., 284 F.3d 302 (1st Cir. 2002) (presumption of consumer deception arises where intent to deceive accompanies impliedly false claim); Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 213 U.S.P.Q. (BNA) 24 (2d Cir. 1981); American Home Products Corp. v. Johnson & Johnson, 577 F.2d 160, 165–166, 198 U.S.P.Q. (BNA) 132 (2d Cir. 1978); McNeilab, Inc. v. American Home Products Corp., 501 F. Supp. 517, 524, 207 U.S.P.Q. (BNA) 573 (S.D.N.Y. 1980); American Brands, Inc. v. R.J. Reynolds Tobacco Co., 413 F. Supp. 1352, 1357 (S.D.N.Y. 1976). *See also* Kutztown Pennsylvania German Festival, Inc. v. Thomas, 50 U.S.P.Q.2d (BNA) 1221 (E.D. Pa. 1999) (since defendant, the successor in interest to German Folk Festival previously held in Kutztown, Pennsylvania, made essentially truthful statements, and since public not deceived, preliminary injunction denied).

[FN12] McNeilab, Inc. v. American Home Products Corp., 501 F. Supp. 517, 525, 207 U.S.P.Q. (BNA) 573, 580 (S.D.N.Y. 1980).

[FN13] McNeilab, Inc. v. American Home Products Corp., 501 F. Supp. 517, 525, 207 U.S.P.Q. (BNA) 573, 580 (S.D.N.Y. 1980).

[FN14] Gillette Co. v. Norelco Consumer Prods. Co., 946 F. Supp. 115 (D. Mass. 1996) (plaintiff's failure to introduce consumer survey is fatal to its contention that nonestablishment claim in suit was false or misleading); Ragold, Inc. v. Ferrero, U.S.A., Inc., 506 F. Supp. 117, 209 U.S.P.Q. (BNA) 835 (N.D. Ill. 1980).

[FN15] Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 213 U.S.P.Q. (BNA) 24 (2d Cir. 1981) (underlying inaccuracies relative to the number and age of women tested, how comparisons were made, and how the results were tabulated found to constitute actionable misrepresentations).

[FN16] Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 277, 213 U.S.P.Q. (BNA) 24, 29 (2d Cir. 1981).

[FN17] Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 213 U.S.P.Q. (BNA) 24 (2d Cir. 1981).

[FN18] *See also* Ragold, Inc. v. Ferrero, U.S.A., Inc., 506 F. Supp. 117, 209 U.S.P.Q. (BNA) 835 (N.D. Ill. 1980) (commercial statement that users of Tic Tac "don't have to give up ... nothin," in the face of an allegation that the consumption of sugar mints carries with it certain carcinogenic consequences, was not misleading or deceptive per se).

[FN19] McNeilab, Inc. v. American Home Prods. Corp., 501 F. Supp. 517, 207 U.S.P.Q. (BNA) 573 (S.D.N.Y. 1980).

[FN20] Id., 501 F. Supp. at 532, 207 USPQ at 586.

[FN21] Vidal Sasson Inc. v. Bristol-Myers Corp., 661 F.2d 272, 213 U.S.P.Q. (BNA) 24 (2d Cir. 1981).

[FN22] R.J. Reynolds Tobacco Co. v. Loew's Theatres Inc., 511 F. Supp. 867, 210 U.S.P.Q. (BNA) 291 (S.D.N.Y. 1980).

[FN23] American Home Prods. Corp. v. Abbott Labs, 522 F. Supp. 1035, 214 U.S.P.Q. (BNA) 351

(S.D.N.Y. 1981).

[FN24] Plough, Inc. v. Johnson & Johnson Baby Prods. Co., 532 F. Supp. 714, 219 U.S.P.Q. (BNA) 34 (D. Del. 1982).

[FN25] Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C., 2006 WL 4448613 (N.D. Ala. 2006), aff'd in part, vacated in part (on validity of patent), rev'd in part on other grounds, 482 F.3d 1347, 82 U.S.P.Q.2d 1293 (Fed. Cir. 2007), petition for cert. filed, 76 U.S.L.W. 3066 (U.S. Aug. 14, 2007) (to establish a violation of the Lanham Act for false advertising, no proof of defendants' intent or willfulness is required); Phoenix of Broward, Inc. v. McDonald's Corp., 441 F. Supp. 2d 1241, 2006-2 Trade Cas. (CCH) P 75401 (N.D. Ga. 2006); Vector Products, Inc. v. Hartford Fire Ins. Co., 397 F.3d 1316 (11th Cir. 2005); Brandt Consolidated Inc. v. Agrimar Corp., 801 F. Supp. 164, 24 U.S.P.Q.2d (BNA) 1341 (C.D. Ill. 1992) (letter to plaintiff's customer including false representation relating to patent rights held to be a § 43(a) violation). *But see* Melea Limited v. Quality Models Ltd., 345 F. Supp. 2d 743 (E.D. Mich. 2004), appeal dismissed, 139 Fed. Appx. 260 (Fed. Cir. 2005) (marketplace representations of patent infringement communicated to defendant's customers are not actionable unless they are made in bad faith). MPT, Inc. v. Marathon Labels, Inc., 2005 WL 2086069 (N.D. Ohio 2005) (court grants defendants' motion to amend answers and assert additional counterclaims since plaintiff's pendente lite communication charging defendants with patent infringement was alleged to have been made in bad faith and thus would survive a motion to dismiss). Mutual Pharmaceutical Co. v. Ivax Pharmaceuticals, Inc., 459 F. Supp. 2d 925, 2006-2 Trade Cas. (CCH) P 75500 (C.D. Cal. 2006) (in the absence of evidence that defendants knew that third-party Internet retailers were equating their products with FDA approval, the court refused to award preliminary relief).

[FN26] Healthpoint, Ltd. v. Allen Pharmaceutical, LLC, 2008 WL 728333 (W.D. Tex. 2008) (in an action for false advertising with respect to allegedly false statements regarding the equivalency and substitutability of defendants' wound-healing ointment to that sold by plaintiffs, the court denied a motion to dismiss and observed that "... the Fifth Circuit has not held that a heightened pleading standard applies to [such claims]"); Wellnx Life Sciences Inc. v. Iovate Health Sciences Research Inc., 516 F. Supp. 2d 270, 2007-2 Trade Cas. (CCH) ¶75916 (S.D. N.Y. 2007) (court granted a motion to dismiss and observed that a claim for false advertising need not comply with the heightened pleading standard); Mintel Learning Technology, Inc. v. Beijing Kaidi Educ., 2007 WL 2288329 (N.D. Cal. 2007) (in its grant of a motion to dismiss for failure to state a claim, with leave to amend, the court found that plaintiff's claim for false advertising was not subject to the heightened pleading standard); John P. Villano Inc. v. CBS, Inc., 176 F.R.D. 130, 1998-1 Trade Cas. (CCH) ¶72133 (S.D. N.Y. 1997) (claims that allege false advertising are not within the ambit of Fed. R. Civ. P. 9(b)); Third Party Verification, Inc. v. Signaturelink, Inc., 492 F. Supp. 2d 1314 (M.D. Fla. 2007) (declaratory judgment-plaintiff survived a motion to dismiss since the complaint was ruled to allege a "*prima facie*" case of false advertising); Williamson v. Rexam Beverage Can Co., 2007 WL 1740000 (S.D. Ohio 2007) (court provisionally granted a motion to dismiss a Lanham Act claim since the complaint failed to specify the what, when and how of defendant's allegedly false statements in the marketplace, even under the more liberal notice-pleading standard); Interface Sec. Systems, L.L.C. v. May, 2007 WL 1300394 (E.D. Mo. 2007) (in assessing the sufficiency of a claim for false advertising, only a short and concise statement of the claim is required); Soilworks, LLC, v. Midwest Industrial Supply, Inc., 2007 WL 704511 (D. Ariz. 2007) (court declined to dismiss a claim for false advertising since plaintiff's claim was not subject to the heightened pleading standard); Gallup, Inc. v. Talentpoint, Inc., 61 U.S.P.Q.2d 1394, 2001 WL 1450592 (E.D. Pa. 2001) (acknowledging that a balance should be struck between the heightened pleading requirement of Rule 9(b) F. R. Civ. P. and its rejection, the court concluded that the complaint's allegations were sufficiently detailed to survive a motion for judgment on the pleadings); H.H. Fluorescent Parts, Inc. v. DM Technology & Energy, Inc., 2005 WL 2972986 (E.D. Pa. 2005) (the court declined to apply Rule 9(b) Fed. R. Civ. P. to false advertising claims under the Lanham Act); Advanstar Communications Inc. v. Dirt Motosports, Inc., 2006 WL 2739700 (N.D. N.Y. 2006) (where the court observed that there was "no

basis to require particularity of pleading in every claim of false advertising," it denied plaintiff's motion to dismiss defendant's counterclaim for false advertising since scienter, a necessary element of a fraud claim, was not a required element of proof in a Lanham Act claim); Kia Motors America, Inc. v. Autoworks Distributing, 2006 WL 2727357 (D. Minn. 2006) (while the court acknowledged that claims for false advertising, since akin to fraud, may be subject to a heightened pleading standard, a claim under Section 43(a)(1)(A) need not meet the specificity requirement of Rule 9(b) Fed.R.Civ.P.), *see* later opinion, Kia Motors America, Inc. v. Autoworks Distributing, 2007 WL 4372954 (D. Minn. 2007) (court denied motion for summary judgment since an issue of fact existed as to whether the automotive parts sold by defendants were materially different from those sold by plaintiff); Select Portfolio Servicing, Inc. v. Evaluation Solutions, L.L.C., 2006 WL 2691784 (M.D. Fla. 2006) (court denied motion to dismiss for lack of subject matter jurisdiction and observed that a claim for false advertising involves "a lower pleading threshold" where the parties are in competition with one another); Synopsys, Inc. v. Magma Design Automation, 2006-1 Trade Cas. (CCH) P 75320, 64 Fed. R. Serv. 3d 847 (D. Del. 2006) (court denied plaintiff's motion to dismiss defendant-counter claimant's answer alleging product disparagement and trade libel under Section 43(a) since defendant's allegations were well within the notice pleading requirement of Fed. R. Civ. P. 8(a) and since defendant was not subject to the heightened pleading requirements of Fed. R. Civ. P. 9(b) regarding allegations of fraud or mistake); John P. Villano Inc. v. CBS Inc., 176 F.R.D. 130 (S.D.N.Y. 1997) (false advertising complaint under Section 43(a) need not plead with particularity required in fraud claims); Max Daetwyler Corp. v. Input Graphics, Inc., 608 F. Supp. 1549, 226 U.S.P.Q. 393 (E.D. Pa. 1985) (although a plaintiff need not satisfy all of the pleading requirements of Rule 9(b) Fed. R. Civ. P., it must provide sufficiently detailed allegations regarding the nature of the accused falsehoods in advertising).

[FN27] Wellness Pub. v. Barefoot, 2008-1 Trade Cas. (CCH) ¶76040, 2008 WL 108889 (D.N.J. 2008) (in its dismissal of plaintiffs' claim for false advertising, the court adopted an "intermediary" standard, one which required more than the plain-statement-notice requirement of Rule 8 of the Red. R. Civ. P., but less than the "heightened pleading" standard of Rule 9(b)); EVCO Technology & Development Co., LLC v. Buck Knives, Inc., 2006-2 Trade Cas. (CCH) ¶75457, 2006 WL 2773421 (E.D. Pa. 2006) (court adopted an "intermediate standard" in ruling on a motion to dismiss); Teragren, LLC v. Smith & Fong Co., 2008 WL 725186 (W.D. Wash. 2008) (court denied plaintiff's motion to dismiss defendant's claim for false advertising and permitted defendant to amend its pleading so as to conform to the Circuit's requirement that such a claim be asserted with "some particularity"); Trans USA Products, Inc. v. Howard Berger Co., Inc., 2008 WL 852324 (D.N.J. 2008) (in its assessment of plaintiff's claims for false advertising and false designation of origin on a motion to dismiss, the court adopted what it characterized as an "intermediate" pleading standard, somewhat higher than that required by Rule 8 and somewhat lower than that imposed by Rule 9, Fed. R. Civ. P.); CardioNet, Inc. v. LifeWatch Corp., 69 Fed. R. Serv. 3d 1687 (N.D. Ill. 2008) (court dismissed defendants' counterclaim for false advertising since their allegations failed to meet the heightened pleading standard of the Rules of Civil Procedure); Midwest Canvas Corp. v. Commonwealth Canvas, Inc., 2008 WL 162757 (N.D. Ill. 2008) (court granted a motion to dismiss certain alleged false advertising claims since the allegations lacked the heightened standard requiring specificity in pleadings alleging fraud); Mintel Learning Technology, Inc. v. Beijing Kaidi Educ., 2007 WL 2288329 (N.D. Cal. 2007) (while the court granted a motion to dismiss a false advertising claim for failure to state a claim, with leave to amend, it nonetheless observed that a claim had been stated as to the corporate defendant, but that plaintiff was required to plead the existence of a civil conspiracy as to various individual defendants); Conditioned Ocular Enhancement, Inc. v. Bonaventura, 458 F. Supp. 2d 704 (N.D. Ill. 2006) (claims for false advertising under the Lanham Act are subject to the heightened pleading standard); MPC Containment Systems, Ltd. v. Moreland, 2006 WL 2331148 (N.D. Ill. 2006) (court dismissed plaintiff's false advertising claim since it did not meet the heightened pleading requirements of Fed. R. Civ. 9(b) which requires, in effect, that a "plaintiff must plead the 'who, what, when [ ] where' [and how] of the alleged fraud."); Buying For The Home, LLC v. Humble Abode, LLC, 459 F. Supp. 2d 310 (D.N.J. 2006) (court declined to award summary judgment to defendants on their counterclaim for false advertising since the allegations lacked sufficient particularity); Pestube Systems, Inc. v. HomeTeam Pest Defense, LLC., 2006-1 Trade Cas. (CCH) P 75304, 2006 WL 1441014 (D. Ariz. 2006) (since the first amended complaint failed to

allege the nature and content of the accusedly false statements and further failed to allege that the subject statements were commercial in nature, court dismisses false advertising claim without prejudice to file an amended pleading so long as it complies with the mandate of Fed. R. Civ. P. 9(b), *see* later opinion, Pestube Systems, Inc. v. HomeTeam Pest Defense, LLC, 2007 WL 973964 (D. Ariz. 2007) (in its partial denial of summary judgment, the court ruled that an issue of fact existed as to whether various statements in promotional materials were literally false); CollegeNet, Inc. v. Xap Corp., 2004 WL 2303506 (D. Or. 2004) (in reliance upon Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 54 Fed. R. Serv. 3d 1032 (9th Cir. 2003) (holding that claims arising under state's unfair business practice laws, but "grounded in fraud," were subject to the heightened pleading requirement of Fed. R. Civ. P. 9(b), the court in *CollegeNet* ruled that Lanham Act claims, based upon allegations that defendants knowingly engaged in deceptive and misleading conduct, were subject to the heightened pleading requirement, *see* related cases, Collegenet, Inc. v. XAP Corp., 2006 WL 2037457 (D. Or. 2006) (court denied summary judgment since issue of fact existed as to whether defendant's privacy-statements were literally false); Collegenet, Inc. v. XAP Corp., 483 F. Supp. 2d 1058, 2007-1 Trade Cas. (CCH) P 75675 (D. Or. 2007) (on bench trial, the court found that plaintiff was entitled to an award of damages without enhancement, flowing from actual deception of college students) and Collegenet, Inc. v. XAP Corp., 2007 WL 1667125 (D. Or. 2007) (court denied motion for entry of judgment under Fed. R. Civ. P. 54(b) on the Lanham Act claim since piecemeal appeals were otherwise likely); Volunteer Firemen's Ins. Services, Inc. v. McNeil and Co., Inc., 221 F.R.D. 388 (W.D. N.Y. 2004) (heightened pleading standard applied where the false advertising claim in suit was essentially a claim for fraud); Max Daetwyler Corp. v. Input Graphics, Inc., 608 F. Supp. 1549, 226 U.S.P.Q. 393 (E.D. Pa. 1985) (the type of misrepresentation asserted in plaintiffs' Lanham Act claim must be pleaded with specificity); and Merix Pharmaceutical Corp. v. GlaxoSmithKline Consumer Healthcare, L.P., 2006 WL 1843370 (N.D. Ill. 2006) (allegation that defendant committed consumer fraud by disseminating false and misleading advertising must be pled with particularity as plaintiff did).

UNFAIRCOMP § 6:3

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United States District Court, W.D. Texas, San Antonio Division.

HEALTHPOINT, LTD. and DPT Laboratories, Ltd., Plaintiffs,

v.

ALLEN PHARMACEUTICAL, LLC, and Pharma PAC, LLC Defendants.

Civil Action No. SA-07-CA-0526-XR.

March 18, 2008.

Joseph A. Bourbois, Saul H. Perloff, Fulbright & Jaworski, LLP, Katharyn Ann Albright Grant, Kaycie L. Wall, Fulbright & Jaworski, L.L.P., San Antonio, TX, for Plaintiffs.

Larkin C. Eakin, Jr., Gene F. Creely, II, Cozen O'Connor, Houston, TX, for Defendants.

ORDER

XAVIER RODRIGUEZ, District Judge.

***1** On this date, the Court considered Defendants' Motion to Dismiss (docket no. 11). After considering the motion and applicable case law, the Court will DENY the motion.

I. Standard of Review

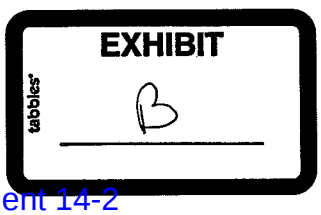
When considering a motion to dismiss for failure to state a claim under Rule 12(b)(6), the Court must generally base its decision only on the pleadings.FED. R. CIV. P. 12(b)(6); *McCartney v. First City Bank,* 970 F.2d 45, 47 (5th Cir.1992). The Court must accept "all well-pleaded facts as true and ... view them in the light most favorable to the plaintiff." *McCartney,* 970 F.2d at 47. "To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead enough facts to state a claim to relief that is plausible on its face." *In re Katrina Canal Breaches Litigation,* 495 F.3d 191, 205 (5th Cir.2007). In other words, "factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atlantic Corporation v. Twombly,* --- U.S. ----, ----, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929 (2007).

II. Factual and Procedural Background

Plaintiffs Healthpoint, Ltd. and DPT Laboratories, Ltd. sued Defendants Allan Pharmaceutical, LLC, and Pharma Pac, LLC, alleging that they violated section 43 of the Lanham Act through false advertising and unfair competition.[FN1] Plaintiffs also assert claims against Defendants for common-law unfair competition and misappropriation.

FN1.15 U.S.C.A. § 1125.

In their Complaint, Plaintiffs explain that they manufacture Xenaderm, a wound-healing ointment, and market it for sale to doctors and healthcare providers. Plaintiffs allege that they have performed experiments and testing on XenaDerm to ensure its efficacy and have expended resources building brand awareness. Plaintiffs allege that Defendants manufacture AllanDerm and market it, directly and by implication, as a generic equivalent to and substitute for XenaDerm. Specifically, Plaintiffs allege that Defendants "falsely promote AllanDerm as a generic substitute for XenaDerm."Compl. ¶ 6. Plaintiffs allege that AllanDerm is not a generic equivalent to or substitute for XenaDerm. Compl. ¶ 18. Plaintiffs further allege that, before launching AllanDerm, Defendants did not perform any tests to determine if it was bioequivalent to or therapeutically equivalent to XenaDerm, nor did they spend the time and resources necessary to ensure that their product would be as pharmaceutically elegant and effective as XenaDerm. Compl. ¶ 12. Based on these facts, Plaintiffs assert four causes of action: (1) violation of Lanham Act § 43(a) (false advertising); (2) violation of Lanham Act § 43(a) (unfair



competition); (3) common-law unfair competition; and (4) common-law misappropriation.

Defendants filed the instant 12(b)(6) motion to dismiss Plaintiffs' claims based on preclusion by the FDA's primary jurisdiction to enforce the FDCA [FN2] and the failure to state a claim upon which relief can be granted. In support of their first basis for dismissal, Defendants assert that all of Plaintiffs' claims turn on the issue of whether AllanDerm is a generic equivalent to XenaDerm, and that question is within the exclusive jurisdiction of the FDA. Defendants contend that courts have held precluded claims based on marketing a product as an alternative, equivalent, or generic alternative, as well as a claim based on failing to sufficiently test a product according to FDA requirements. In support of their second basis for dismissal, Defendants also argue that Plaintiffs' claims should be dismissed because Plaintiffs have failed to allege specific acts or misrepresentations by Defendants that have caused or threaten to cause injury to Plaintiffs. Defendants assert that Plaintiffs have not alleged actual facts from which one might reasonably believe that the products are not in fact equivalent. Defendants further contend that Plaintiffs' failure to plead "specific, actual, and actionable statements" in advertising requires dismissal of the Lanham Act claims.

FN2.21 U.S.C.A. §§ 301-395 (West 2007).

***2** Plaintiffs respond that they are not alleging any violation of FDA regulations, but are simply asserting claims based on "false and misleading claims of generic equivalence and substitutability" that Defendants have made. Plaintiffs argue that Defendants' representations are false because they have no studies or comparative clinical evidence to support them, AllanDerm is not rated as equivalent in the Orange Book [FN3], and AllanDerm does not work as well as XenaDerm. Plaintiffs assert that courts have consistently held that false and misleading misrepresentations of generic equivalence and substitutability are actionable under the Lanham Act even if the truth of the facts underlying them may be generally within the purview of the FDA, and courts may use the FDA definition of equivalence to determine the falsity of these statements.

FN3. According to the Complaint, "To assist pharmacists and others in making drug product selection decisions, the FDA regularly publishes a list of interchangeable prescription drugs in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as 'The Orange Book.' " Compl. ¶ 22. However, the Orange Book does not list every drug. *Id.* It does not list XenaDerm, and thus cannot list AllanDerm as a generic to XenaDerm. *Id.*

III. Analysis

The Court first turns to the issue of whether Plaintiffs have stated a claim with sufficient specificity to survive a 12(b)(6) motion. The Court will then determine whether Plaintiffs' claims are precluded by the FDA's primary jurisdiction to interpret and enforce the FDCA.

A. Failure to state a claim

Defendants contend that, since the Plaintiffs admit that they have no evidence regarding whether AllanDerm is in fact generic or equivalent to XenaDerm, Plaintiffs' claim is speculative. Further, Defendants contend that "the Original Complaint fails to allege any specific action, or omission to act, by Defendants that has caused or threatens to cause injury to Plaintiffs. Instead, a careful reading of the Original Complaint reveals an interweaving of suppositions and innuendo about Defendants with actions that 'could' or 'might' be taken by a nationwide complex of learned and extremely sophisticated intermediary consumers such as medical doctors, pharmacists, nurses, healthcare facilities, and distributors of medicines and medical products."Further, Defendants' motion complains that "Plaintiffs' Original Complaint does not plead

one single instance of actual confusion; not even one instance of any person raising a question concerning any aspect of the products at issue" and "does not attach a single exhibit or incorporate a single document supporting its allegations of harm or threatened harm."

In their Reply, Defendants emphasize that Plaintiffs have failed to "plead specific, actual, actionable statements in advertising" to support a Lanham Act claim. Relying on *Mylan Labs. v. Matkari,* 7 F.3d 1130, 1139 (4th Cir.1993), Defendants argue that, "in order to state a claim for relief under § 43 of the Lanham Act, [a plaintiff is] required to point to some claim or representation that is reasonably clear from the face of the defendants' advertising or packaging inserts."However, Defendants contend, "The Plaintiffs' Complaint does not contain even one allegation of a false or misleading affirmative statement in advertising or marketing by the Defendants."Instead, Defendants argue, "The Plaintiffs' real complaint seems to be that some medical professionals have concluded-without any action at all by the Defendants-that the two products are equivalent, and that the Defendants have not tried to correct this conclusion."Defendants assert that "[t]he Lanham Act forbids false advertising, but does not require that the Defendants correct an allegedly wrong impression that they did not create by some affirmative act. Because the Plaintiffs have not (and cannot) allege any specific, false or misleading statement by the Defendants their claims must be dismissed."[FN4]

> FN4. Relying on a False Claims Act case from the Fifth Circuit, Defendants argue that Rule 9's particularity requirements apply, and that "[t]he time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby must be stated in a complaint."However, the Fifth Circuit has not held that a heightened pleading standard applies to false advertising claims under § 43(a) of the Lanham Act.

***3** As noted, Plaintiffs assert four claims against Defendants: (1) false advertising under section 43(a) of the Lanham Act; (2) unfair competition under section 43(a) of the Lanham Act; (3) common-law unfair competition (under Texas law); and (4) common-law misappropriation (under Texas law). Section 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125, provides in part:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-
>
> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). Courts have interpreted this section of the Lanham Act as providing "protection against a 'myriad of deceptive commercial practices,' including false advertising or promotion." *Pizza Hut, Inc. v. Papa John's Int'l, Inc.,* 227 F.3d 489, 495 (5th Cir.2001).

To recover under the Lanham Act for false advertising, a plaintiff must prove the following elements: "(1) a false or misleading statement of fact about a product; (2) a statement which actually deceived or had the capacity to deceive a substantial segment of

potential consumers; (3) a material deception in that it was likely to influence a consumer's purchasing decision; (4) the product was in interstate commerce; and (5) plaintiff had been or was likely to have been injured as a result of the statement at issue."*Id.* There are two types of actionable statements for Lanham Act purposes: statements that are literally false and statements that, while not literally false, implicitly convey a false impression or are misleading and likely to deceive consumers. *Id.* If the statement is shown to be misleading, the plaintiff must also produce evidence of the statement's impact on consumers, referred to as "materiality." *Healthpoint, Ltd. v. River's Edge Pharms., L.L. C.,* Civ. A. No. SA-03-CV-984-RF, 2005 WL 356839 (W.D.Tex. Feb.14, 2005).

Healthpoint also asserts an unfair competition claim under Section 43(a), as well as under Texas common law.[FN5]Unfair competition under Texas law "is the umbrella for all statutory and nonstatutory causes of action arising out of business conduct which is contrary to honest practice in industrial or commercial matters." *Taylor Publishing Co. v. Jostens, Inc.,* 216 F.3d 465, 486 (5th Cir.2000). The category of unfair competition includes a number of types of objectionable trade practices, including trademark infringement, dilution of good will, misappropriation of business value, "palming off," and theft of trade secrets. *Healthpoint, Ltd. v. River's Edge Pharmaceuticals, LLC,* No. SA-03-CV-984-RF, 2005 WL356839 (W.D.Tex. Feb. 14, 2005). The tort requires that the plaintiff show an illegal act by the defendant that interfered with the plaintiff's ability to conduct its business. *Id.* (citing *Taylor Pub.,* 216 F.3d at 486). Although the illegal act need not necessarily violate criminal law, it must at least be an independent tort.*Id.* As in *Healthpoint v. River's Edge,* because Plaintiffs' allegations in support of their unfair competition claim are essentially the same as those in support of their false advertising claim, the Court construes the Complaint as alleging a primary tort of false advertising with a dependent or supplemental claim for unfair competition, and thus the unfair competition claim is dependent upon the false advertising claim. *Id.; see also Healthpoint v. Ethex,* Civ. A. No. 01-CV-646-OG, 2004 WL 2359420 (W.D.Tex. July 14, 2004) ("Healthpoint's allegations in support of its claim of common law unfair competition are those also alleged for false advertising in violation of the Lanham Act. Accordingly, the claim for common law unfair competition will be analyzed under the elements of the claim of false advertising in violation of the Lanham Act.") [FN6]

> FN5. As noted by Plaintiffs, absent an argument that there are differences between the federal and state versions of unfair competition claims, courts in the Fifth Circuit analyze these claims together. *See King v. Ames,* 179 F.3d 370, 374 (5th Cir.1999).
>
> FN6. Relatedly, Defendants do not directly address the misappropriation claim in their motion to dismiss, other than to assert that it falls with the Lanham Act claim.

***4** Plaintiffs argue that their claims for false advertising and unfair competition are supported by their allegations that, in their commercial advertising, Defendants have made false and misleading statements of fact concerning AllenDerm and XenaDerm, that the ads have deceived customers that AllanDerm is equivalent to and substitutable for XenaDerm, that the deception is material, having lead drug buyers and pharmacies to substitute AllanDerm for XenaDerm, and that Healthpoint has been injured as a result. As a result, Plaintiffs argue that they have adequately stated a claim for false advertising under the Lanham Act, and dependent claims of unfair competition under the Lanham Act and common law.

Plaintiffs allege that "Allan falsely promotes AllanDerm as a generic substitute to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations and/or others."Compl. ¶ 6. Plaintiffs allege that they have "expended enormous re-

sources developing XenaDerm and building brand awareness."*Id.* ¶ 9. Plaintiffs allege that Allan "manufactures, formulates, and distributes what it calls 'generic' or 'brand-equivalent' versions of brand-name prescription drugs."*Id.* ¶ 10.Plaintiffs allege that, in 2006, Allan decided to create a "knock-off" of XenaDerm and contacted Pharma-Pac to manufacture it. *Id.* ¶ 11."Upon information and belief, Allan began marketing its knock-off ointment product as 'AllanDerm-T Ointment" in 2006."*Id.* ¶ 12.

Further, "[u]pon information and belief, prior to launching AllanDerm, Defendants did not perform any tests to determine if it was bioequivalent or therapeutically equivalent to XenaDerm, nor did Defendants spend the time and resources necessary to ensure that their product would be as pharmaceutically elegant and effective as XenaDerm."*Id.* ¶ 12."Despite the absence of clinical equivalency testing, Allan nevertheless markets AllanDerm ... as a generic equivalent and substitute for XenaDerm."*Id.* ¶ 13."Upon information and belief, Allan has had AllanDerm linked to XenaDerm in drug dispensing databases and price systems that represent a major drug marketing communications channel to pharmacists and chain store buyers, and are used by pharmacists to decide which drug product to dispense when filling a prescription."*Id.* Plaintiffs further allege that, in its advertising and promotion to drug databases and pricing systems, "Allan has made no effort to differentiate AllanDerm from XenaDerm other than on the basis of price."*Id.* ¶ 14."Upon information and belief, in commercial advertising and promoting, Allan states and implies that AllanDerm is a generic version of XenaDerm and labels AllanDerm as a generic equivalent to XenaDerm."*Id.* Further, "AllanDerm does not inform drug databases and pricing systems, wholesalers, distributors, pharmacies or pharmacists that there are no comparative studies showing that its ointment is therapeutically equivalent or bioequivalent to XenaDerm."*Id.* Plaintiffs allege that, "[b]ased upon Defendants' commercial advertising and promotion, drug databases and pricing systems, as well as wholesalers, distributors, formularies, and retail pharmacy chains have 'linked' AllanDerm as a generic equivalent to XenaDerm" and "AllanDerm is now substituted as a generic for XenaDerm in pharmacies."*Id.* ¶ 17.Plaintiffs allege that "[t]his could not occur unless Defendants had successfully created the false impression among drug databases and pricing systems, wholesalers, distributors, formularies, retail pharmacy chains and pharmacists that AllanDerm is genuinely generic to and substitutable for XenaDerm."*Id.*

***5** Plaintiffs further allege that AllanDerm is not a generic to or substitute for XenaDerm. *Id.* ¶ 23."Upon information and belief, Defendants have not performed or commissioned any studies comparing the effectiveness of their ointment to XenaDerm and have no clinical evidence that AllanDerm is bioequivalent or therapeutically equivalent to XenaDerm."*Id.*[FN7]"Additionally, upon information and belief, AllanDerm is not bioequivalent or therapeutically equivalent to XenaDerm, and produces inferior clinical results compared to XenaDerm."*Id.*

> FN7. Plaintiffs' Complaint states that, "Generic drugs are *therapeutically equivalent* to their branded rivals. To be *therapeutically equivalent,* the products must be *pharmaceutically equivalent*-e.g., have the same active ingredients, strength, and dosage form-and they must be *bioequivalent*-deliver the active ingredients to the body at the same rate and in the same amount."Compl. ¶ 19 (emphasis in original).

Plaintiffs allege that they have been harmed because Defendants' marketing efforts have misled consumers into believing that AllanDerm is a generic to XenaDerm, and substitutions of inferior AllanDerm for XenaDerm are eroding XenaDerm sales and goodwill. *Id.* ¶ 25.

Plaintiffs allege that Allan's advertisements and promotional claims about AllanDerm are literally false and/or impliedly false and misleading because

AllanDerm is not generic to or substitutable for XenaDerm. *Id.* ¶ 28.Plaintiffs further allege that Allan is liable under section 43(a) because it knows or has reason to know that entities are falsely describing AllanDerm as a generic equivalent to and substitute for XenaDerm, but continues to supply XenaDerm to those entities. *Id.* ¶ 29.Plaintiffs allege that Pharma Pac is liable because it knows or has reason to know of Allan's false or misleading advertising of AllanDerm as a generic equivalent or substitute for XenaDerm, but continues to supply AllanDerm to those entities. *Id.* ¶ 30.

Boiled down to its essence, Plaintiffs' false advertising claim is based on the allegation that Allan falsely advertises and promotes AllanDerm as a generic equivalent and substitute for XenaDerm, but (1) Allan performed no testing to determine if AllanDerm was bioequivalent or therapeutically equivalent to XenaDerm, (2) Defendants did not spend the time and resources necessary to ensure that their product would be as pharmaceutically elegant and effective as XenaDerm, (3)AllanDerm is not listed as a generic equivalent in the Orange Book, and (4)AllanDerm does not work as well as XenaDerm and is inferior to XenaDerm. The only specific false representation listed in the Complaint is that in paragraph 14: "Upon information and belief, in commercial advertising and promoting, Allan states and implies that AllanDerm is a generic version of XenaDerm and labels AllanDerm as a generic equivalent to XenaDerm."In a footnote to the Complaint, Plaintiffs state that much of the marketing for a generic drug occurs " 'under the radar' in targeted communications with drug wholesalers, retailers and others, who are encouraged to 'link' the generic product to the branded drug in their databases."Plaintiffs state that they are not privy to these communications and that "there are many unseen and unheard sales pitches and additional pieces of evidence that will only come to light through discovery."

***6** In *Mylan Labs v. Matkari,* the Fourth Circuit concluded that the plaintiff sufficiently stated a false advertising claim by alleging that the defendant "falsely represented" that its product was "bioequivalent to its innovator counterpart and other approved generic equivalents," that the product was "entitled to an AB rating" from the FDA, or that the product was the "generic alternative" to the innovator drug. *Mylan Labs.,* 7 F.3d at 1138. In support of those claims, the plaintiff alleged that FDA approval had been obtained through fraud and ultimately was withdrawn, that the data for the bioequivalence studies had been falsified or was seriously unreliable, and that bioequivalence studies had not been performed or had been performed on a drug that was manufactured differently than the advertised drug. *Id.* In short, the Fourth Circuit held, the plaintiff "set forth in the complaint sufficiently particularized allegations of false or misleading misrepresentations to sustain, for now, Count 3."*Id.*Nevertheless, the Court concluded that Mylan's claims that the defendants' falsely represented that their drugs had been "properly approved by the FDA" failed. This was not because such a false representation would not be actionable, but because Mylan did not point to any statement or representation in the defendants' advertising that declared such "proper FDA approval." The court rejected Mylan's assertion that the very act of placing a drug on the market, with standard package inserts often used for FDA-approved drugs, somehow falsely implied that the drug had been "properly approved by the FDA" as "too great a stretch under the Lanham Act" that would, "in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the [FDCA]."*Id.* at 1139.Thus, the court held, "[i]n order to state a proper claim for relief under § 43(a) of the Lanham Act, Mylan was required to point to *some* claim or representation that is reasonably clear from the face of the defendants' advertising or package inserts."*Id.*

The Court finds that Plaintiffs have alleged a specific false or misleading misrepresentation in Defendant's commercial advertising-that Allan states and implies that AllanDerm is a generic equivalent

of XenaDerm, when in fact it is not. The fact that Plaintiffs do not have the exact advertisement at this early stage of the litigation is not sufficient to warrant dismissal, as the facts alleged in the Complaint are sufficient to bring the allegations beyond the speculative level. Other district court decisions have considered substantially similar allegations and found them sufficient to survive a 12(b)(6) motion to dismiss. *See Axcan ScandiPharm, Inc. v. Ethex Corp.,* 2007 WL 3095367 (D.Minn.2007) ("Stated differently, Axcan has pleaded the 'who [the Defendants], what [false advertising], where [in ads targeted to drug databases, wholesalers, and pharmacies], when [since the late 1990's], and how [falsely claiming their drugs are generic equivalents or substitutes]' of its claims.") (brackets in original); *Solvay Pharmaceuticals, Inc. v. Global Pharmaceuticals,* 298 F.Supp.2d 880, 886 (D.Minn.2004) ("The Complaint asserts that Defendants have made false and misleading representations in advertising and marketing regarding the substitutability of Lipram for Creon. These assertions of false and misleading representations are sufficiently particularized to facilitate Defendants' ability to respond to and prepare a defense to the allegations brought against them.").

***7** For similar reasons, the Court finds that Plaintiffs have adequately stated a claim for unfair competition. Plaintiffs need not attach proof of actual confusion to their Complaint. It is sufficient that they have alleged that the targeted audience was actually misled and that these entities have linked AllanDerm and XenaDerm. *See* Complaint ¶¶ 17, 25.

The Court concludes that Plaintiffs' Complaint sufficiently states a claim to survive a 12(b)(6) motion to dismiss. The Court thus turns to the more difficult issue of whether this Lanham Act claim infringes on the FDA's primary jurisdiction.

B. Preclusion by the FDA's primary jurisdiction to enforce the FDCA

Defendants argue that Plaintiffs' claims must be dismissed because they are precluded by the FDCA and the FDA's primary jurisdiction to enforce the FDCA. The overlap and potential conflict between the Lanham Act and the FDCA is not a new issue. As one court recently explained, "The FDCA and the Lanham Act overlap to the extent that both regulate drug products in the marketplace. Courts have recognized the potential conflict between the two Acts and have struggled to define the proper scope of each law. Courts have come to the general conclusion that the FDA's enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims." *Axcan Scandipharm, Inc. v. Ethex Corp.,* 2007 WL 3095367 (D.Minn.2007). One may not bring a Lanham Act claim that "requires direct application or interpretation of the FDCA or FDA regulations." *Healthpoint, Ltd. v. Ethex Corp.,* 273 F.Supp.2d 817, 837 (W.D.Tex.2001). Therefore, Plaintiffs' Lanham Act claims are precluded if direct application or interpretation of the FDCA or FDA regulations is necessary to prove a crucial element of the claim. *Id.* at 838.However, "[t]here is no single, bright-line test to distinguish sustainable from non-sustainable claims." *Id.* at 837.

In *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.* (*Grove Fresh I*), 720 F.Supp. 714 (N.D.Ill.1989), the plaintiff brought a Lanham Act claim in which it accused the defendant of falsely representing that its orange juice was made from "100% orange juice." In denying the defendants' motion to dismiss, the court stated that the plaintiff was using the FDA regulation defining "orange juice from concentrate" in order to "establish the standard or duty which defendants allegedly failed to meet" and that "[n]othing prohibits Grove Fresh from using the FDCA or its accompanying regulations in that fashion." *Id.* at 716.The court carefully distinguished between a claim based "solely on the FDCA or FDA regulations" and a claim that uses an FDA regulation to establish the standard for finding a Lanham Act violation:

> In the instant case, ... Grove Fresh does not base its claim solely on the FDCA or FDA regulations. Grove Fresh alleges that defendants have violated section 43(a) of the Lanham Act. Even without the FDA regulation defining "orange juice from concentrate," Grove Fresh could attempt to establish a violation of section 43(a). Grove Fresh would simply need to provide other evidence establishing the proper market definition of "orange juice from concentrate." Thus, Grove Fresh has asserted an independent basis for its claim ....

***8** 720 F.Supp. at 716.

However, just two months later, the same court (before a different judge) in *Grove Fresh Distributors, Inc. v. Everfresh Juice Co.,* 1989 WL 152670 (N.D.Ill.1989) (*"Grove Fresh II"*), concluded that Grove Fresh could not rely on the FDCA definition of "100% pure orange juice from concentrate" in proving its Lanham Act claim. *Id.* at *3. Grove Fresh alleged that Everfresh was marketing its product as 100% orange juice from concentrate even though it contained other ingredients, and brought a Lanham Act claim based on defendant's noncompliance with the relevant FDCA definition for labeling a product 100% orange juice from concentrate. The court denied the motion to dismiss, but limited the plaintiff's ability to prove its claims by referencing the FDA regulations:

> Grove Fresh argues that it does not really invoke the FDCA, it relies on the FDCA indirectly, solely (or merely) to establish the standard which defendants failed to meet. Distinctions between direct and indirect must sometimes be made but they are difficult to defend and ought to be avoided. Reliance upon the FDCA to establish a standard which defendant must meet is a very substantial use of the FDCA. Where Congress has precluded private causes of action under the FDCA, we find it difficult to justify the use of the FDCA to establish a crucial element of a private cause of action under the Lanham Act.... Grove Fresh cannot base its Lanham Act claim upon the violation of the FDCA.
>
> This is not, however, necessarily fatal to the Lanham Act claim. Judge Bua has held, and I agree, that "[e]ven without the FDCA regulation defining 'orange juice from concentrate', Grove Fresh could attempt to establish a violation of section 43(a) ... Grove Fresh would simply need to provide other evidence establishing the proper market definition of 'orange juice from concentrate.' "*Grove Fresh v. Flavor Fresh,* 89 C 1114 (N.D.Ill.1989). This may not be a very promising course for Grove Fresh to undertake. There may, in fact, be no proper market definition of "100% Orange Juice from Concentrate" outside of the FDCA and its regulations, or, if there is, it may be inconsistent with the regulations definition and thus preempted by that definition. Striking all reference to the FDCA regulations leaves a still valid (if hard to prove) complaint. The Motion to Dismiss the first count in each complaint is denied.

In *Mylan Laboratories, Inc. v. Matkari,* 7 F.3d 1130, 1138 (4th Cir.1993), the court declined to dismiss a Lanham Act claim alleging false statements of bioequivalency. The court explained that the plaintiff could prevail on such a claim by proving that the test results supporting the statement were " 'not sufficiently reliable to permit one to conclude with reasonable certainty that they established' the claim made."In finding the allegations sufficient to survive the motion to dismiss, the court took particular notice of Mylan's accusations that defendant "falsely represented" its product as "bioequivalent" or a "generic alternative," that it deserved an "AB" rating from the FDA, and that studies to prove bioequivalence had either not been performed or had been falsified. However, the court dismissed the plaintiff's claim that the defendant's placing of the product on the market implied FDA approval because the claim lacked the false representation necessary for a Lanham Act claim, and was thus simply a disguised attempt to enforce the FDCA.

***9** In *Healthpoint, Ltd. v. Ethex Corp.,* 273

F.Supp.2d 817 (W.D.Tex.2001), the court considered the FDA's primary jurisdiction over several claims, including a claim that Ethex falsely advertised its product as an alternative to plaintiff's product. *Id.* at 824.Specifically, the plaintiff complained that the defendant had made false and misleading statements that its ointment was "a generic form of, the same as, a substitute for, an alternative to, a therapeutic equivalent to or substitute for" plaintiff's ointment. *Id.* at 830.The court concluded that the underlying question of whether Ethezyme is a "generic" to Accuzyme is an issue "committed to the FDA" that the district court should decline to address. *Id.* at 841-42.Healthpoint argued "that Ethex has not demonstrated that Ethezyme is therapeutically or bioequivalent to Accuzyme and, therefore, Ethex should not be allowed to suggest that Ethezyme is freely substitutable, under most state laws, as 'generically' equivalent." *Id.* at 842-43.Ethex argued that to allow Healthpoint to pursue its claim "would require Ethex 'to prove bioequivalence to Accuzyme, ... [and] ... in effect, Ethex would be required to submit an ANDA [Abbreviated New Drug Application] to the FDA for Ethezyme when there is no procedure that would allow for such filing.'" The court stated that, "[i]t seems clear that in addressing claims of 'equivalent to' or 'alternative to,' the Court should not change the FDA's definitions of such related terms of art as 'pharmaceutical equivalent,' 'therapeutic equivalents,' 'bioequivalence,' and 'pharmaceutical alternative.' " *Id.* at 843."New definitions of FDA terms would undercut national uniformity regarding federal laws regulating the drug market or would confuse the public and undermine confidence in the drug supply in general and generic drugs in specific."*Id* . Thus,

> Although Lanham Act or related common law claims that concern whether Ethezyme is "the same as" Accuzyme-to the extent that determination requires a simple comparison of ingredients and does not entail a decision on whether sodium metabisulfite should be listed as an active ingredient-appear to be properly before the District Court, a determination of whether Ethezyme is "equivalent" to Accuzyme appears to be inextricably linked to the determination of whether Ethezyme is being marketed lawfully, a matter within the exclusive enforcement domain and "particular expertise" of the FDA. Similarly, the "task of identifying in the first instance whether one drug is the generic equivalent of another" belongs to the FDA ... The term "alternative" is less problematic ... [it] does not imply identity or equivalence.

Id. at 843-44.Based on this reasoning, the court declined to consider the issue of whether Ethezyme was in fact a "generic" or "equivalent" product to Accuzyme, but held that claims based on allegedly false statements that the products were the "same" or that one was a "high quality alternative" were properly before the court. *Id.* at 846 nn. 140-41.The court recognized that Ethex's witnesses testified that there are "generic alternatives" that do not need to be approved by the FDA and that the term "generic" may be used "without confusion with respect to drugs that are similar but not necessarily therapeutically equivalent," but noted that it is in the FDA's interest to ensure that "only one definition of FDA terms of art, such as 'therapeutically equivalent' and 'generic,' is used in the context of drug approval, acceptance and use."*Id.* at 866 (citations omitted). The Court ultimately enjoined Ethex from including in further print advertisements comparing Ethezyme to Accuzyme language that "neither brand nor generic papain-urea compounds are subject to FDA approval or rating," because, in the context of other representations, it was misleading and inconsistent with its claim that Ethezyme is a "generic" equivalent. *Id.* at 866."The over-all effect [was] to create the misleading impression that Accuzyme is the 'brand' and Ethezyme is a 'generic substitute for Accuzyme, when it has not been determined that Ethezyme is a 'generic' alternative to Accuzyme."*Id.* at 867.[FN8]

> FN8. In a later order by Judge Garcia concerning Magistrate Judge Mathy's recom-

mendation on the preliminary injunction and a motion to stay, the court stated,

> Ethex Corporation further objects to the Magistrate Judge's recommendation that the Court should abstain from hearing the issue of whether Ethezyme is, in fact, "generic" or "equivalent" to Accuzyme, but that it may consider whether representations that Ethezyme is "generic" or "equivalent" to Accuzyme without sufficient substantiation (i.e. supporting test data) are false or misleading. Ethex contends that these two issues are not distinguishable. (Dkt.# 225, pp. 19-20). On the other hand, Healthpoint contends the issues are distinguishable because the first issue (whether Ethezyme is, in fact, "generic or equivalent to" Accuzyme) is a regulatory question to the extent such terms must be interpreted or defined by the FDA, whereas the second issue is a marketing question (whether it is appropriate for Ethex to market Ethezyme as a generic or equivalent drug without test data to support such representation). (Dkt.# 245, pp. 10-11). Although the Court agrees that the distinction between such issues may be blurry at times, the Magistrate Judge analyzed these issues thoroughly, and the Court does not believe the facts or law compel a different conclusion.
>
> *Healthpoint v. Ethex,* Civ. A. No. 00-757-OG, 2001 WL 34897840 (W.D.Tex. Aug.3, 2001).

***10** *Healthpoint v. Stratus Pharmaceuticals,* 283 F.Supp.2d 769, 792 (W.D.Tex.2001), presented claims based on false representations that defendant's products were "generic" to plaintiff's and could be substituted for prescriptions of plaintiff's products. Though noting that the question whether two products are generic is best left to the FDA, the court concluded that "a drug manufacturer making a claim that a non-approved drug is 'generic' to or a 'generic equivalent' of another non-approved drug must use the FDA's definition of 'generic' and, when such a representation is challenged, as here, through a Lanham Act false advertising claim with specific allegations that the use of the terms is false and unsubstantiated, must defend and be prepared to demonstrate why it stated that its drug is a 'generic equivalent,' that is, is 'identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.'"*Id.* at 792.The court explained:

> The primary jurisdiction of the FDA would not appear to bar a court from deciding Healthpoint's false advertising claim that Stratus has made false claims of "generic equivalence" or "bioequivalence" and has allegedly falsely represented that Kovia and Ziox have the "same ingredients" or the "same active ingredients." There is a distinction, on the one hand, between respecting the FDA's primary jurisdiction to determine in the first instance whether a drug is lawfully marketed, "generic," "bioequivalent," "therapeutically equivalent," "pharmaceutically equivalent" and, on the other hand, a Lanham Act claim that a false statement has been made about a product. Even though the FDA has not required Stratus to demonstrate the equivalence of Kovia to Accuzyme or the equivalence of Ziox to Panafil White, Stratus is not free to make false or misleading statements about its product. To hold to the contrary would mean that an administrative scheme could eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction. For example, if Stratus represents that its two ointments are "bioequivalent," "generically equivalent," "equivalent" or have "the same active ingredients" or "the same ingredients" or "the same active ingredients in the same amounts," consumers and competitors have a right to expect that such representations have factual support and

> the Lanham Act provides a vehicle to enforce that expectation.

Id. at 792-93 (footnotes omitted). The court stressed that Healthpoint was not alleging that Stratus had falsely implied FDA approval, but instead the claims were "of false or misleading comparisons between two specific products in the context of comparative advertising and promotion relating to whether one drug can be substituted for another under state law."*Id.* at 793.

Later in the litigation, the court considered motions for summary judgment. The court considered whether Stratus's use of the term "generic" was false, "[s]etting aside the questions of whether under the FDA standards, Kovia and Ziox are generics for Accuzyme and Panafil, questions for the FDA and not for the Court." *Healthpoint v. Stratus Pharmaceuticals, Inc.,* 273 F.Supp.2d 871, 891 (W.D.Tex.2001). The court noted that the record reflected that defendant had attempted to market its product in such a way as to suggest that the products were interchangeable, but "[w]hen and what Stratus knew of the differences in the products and whether even with the knowledge Stratus continued to market Kovia as a generic for Accuzyme are questions of fact."*Id.*

***11** In *Ethex Corporation v. First Horizon Pharmaceutical Corporation,* 228 F.Supp.2d 1048 (E.D.Mo.2002), First Horizon claimed that Ethex illegally sought to have its products listed as generic versions of First Horizon's product in pharmaceutical drug databases. *Id.* at 1051.Neither party's products (prenatal vitamins) were subject to FDA approval. *Id.* at 1052.First Horizon argued that calling the vitamins generic "is an implicit representation that the vitamins have met the test of bioequivalency and therapeutic equivalency." *Id.* at 1053.The court discussed the Third Circuit's decision in *Sandoz Pharmaceuticals Corp. v. Richarson-Vicks, Inc.,*[FN9] stating that it stands "for the proposition that a court should not find a label to be literally false if the complaining party has made no showing other than a proffered interpretation of an agency's regulations" and "cautions courts not to determine preemptively how an administrative agency will interpret and enforce its own regulations."*Id.* The court also discussed *Grove Fresh I,* noting that the court allowed the plaintiff to go forward with its Lanham Act claim because the plaintiff was using the FDA regulation merely to establish the standard or duty, and that, because the plaintiff could have stated a Lanham Act claim without the FDA definition by simply providing other evidence establishing the market definition of the term, the plaintiff was not relying solely on the FDA regulation to pursue its false advertising claim. *Id.* at 1054.The court then concluded that, based on the precedents and the specifics of the defendants' counterclaim, the claim was precluded:

FN9. 902 F.2d 222 (3d Cir.1990).

> While Defendant insists that it is not attempting to privately enforce the provisions of the FDCA, the express language of its own counterclaim speaks to the contrary. The touchstone of Defendant's argument focuses on the fact that the word "generic" implies FDA endorsement and certain FDA-defined concepts. *See* Defendant's Answer and Counterclaims ¶ 43 (unless a drug has an approved ANDA, it cannot be properly and correctly represented to be generic to another drug), ¶ 57 (the term generic as used in the pharmaceutical industry presupposes FDA approval), ¶ 63 (marketing vitamins as generic infers equivalence and interchangeability). Defendant argues that pharmacists, upon seeing Plaintiffs' vitamins marketed as generic, were confused into believing that they could lawfully substitute Plaintiffs' version of the drug. But the pharmacists could only be confused if "generic" is taken as an implicit representation that the product meets FDA standards of bioequivalence and therapeutic equivalence. The decisions in this area have refused to allow plaintiffs to state a claim based on implicit representations of FDA approval; this Court thinks it inappropriate, then, to sustain a Lanham Act claim based on a representation which some-

how implied FDA definitions.

The FDA has not required either parties' drugs to obtain FDA approval. Thus, neither party has tested, nor were they required to test their drugs for bioequivalence and therapeutic equivalence. A pharmacist should know this if he looked in the Orange Book. Moreover, no federal statute or FDA regulation has defined the term "generic." Unlike in *Grove Fresh,* where the term at issue was clearly defined in an FDA regulation, this Court would be forced to determine FDA policy in order to determine the truth or falsity of the "generic" nomenclature. This Court agrees with the majority of courts that have handled this issue that this type of claim is better left to the FDA who has the expertise in enforcing and interpreting its own complicated regulations. This is especially true in this case where the FDA has not even required prenatal vitamins to meet any standards.

***12** For these reasons, to the extent Defendant claims a violation of the Lanham Act based on Plaintiffs' marketing their vitamins as generic, or alternatives to Defendant's product, or inducing illegal substitution, that portion of the Counterclaim is dismissed.

Id. at 1055.

In *Solvay Pharmaceuticals, Inc. v. Global Pharmaceuticals ("Solvay I"),* 298 F.Supp.2d 880 (D.Minn.2004), Solvay alleged that defendant was falsely marketing Lipram as a substitute for its pancreatic enzyme supplement Creon. Solvay alleged that defendants were "marketing their Lipram products either expressly or by implication as 'generic' versions of Creon, even though Lipram is not, in fact, equivalent to Creon." *Id.* at 882.Neither Creon nor Lipram appeared in the Orange Book, and neither was subject to FDA approval. Solvay alleged that the defendants had not studied whether Lipram is a therapeutic equivalent of Creon and that it was not pharmaceutically equivalent to Creon. *Id.* Defendants moved to dismiss the suit as precluded by the FDCA. The court found *Mylan* to be instructive, noting that the *Mylan* court "would not sustain claims for false representations of FDA approval, but did allow claims related to allegedly false statements regarding bioequivalence or generic equivalence." *Id.* at 884.The court then concluded that Solvay's claims "are not related to FDA approval, or lack thereof," but were claims "based upon Defendants' allegedly false marketing assertions that the Lipram supplements are 'generic,' 'comparable,' 'substitutable' or 'equivalent' to Solvay's Creon line."*Id.* Because neither Lipram nor Creon were listed in the Orange Book, "FDA approval is not required in order to substitute the products or to make a determination of bioequivalence or therapeutic equivalence" and "the FDA [did] not regulate the substitution of Lipram for Creon in any manner."*Id.* Thus, "[w]ithout any claims or factual assertions that tie Solvay's claims to FDA approval, Solvay has not attempted to privately enforce the provisions of the FDCA."*Id.* at 885.The Court distinguished *Ethex v. First Horizon,* noting that the "*Ethex* court focused on the express language of the counterclaims, noting that '[t]he touchstone of Defendant's argument focuses on the fact that the word 'generic' implies FDA endorsement and certain FDA-defined concepts."*Id.* In contrast, "Solvay's claims [did] not relate to or allege false assertions of FDA approval" and thus "the Court does not run the risks expressed in *Ethex* of usurping the FDA's approval or encroaching upon FDA jurisdiction when no FDA regulatory approval over the substitution is either alleged or in effect."*Id.*

In *Solvay Pharmaceuticals, Inc. v. Ethex Corp. ("Solvay II"),* Civ. A. No. 03-2836, 2004 WL 742033 (D.Minn.2004),[FN10] the court declined to dismiss false advertising claims based on the allegation that Ethex had marketed its "products either expressly or by implication as 'equivalent,' 'comparable,' and 'generic' versions of Creon."Ethex argued that whether the drugs were in fact equivalent was an issue to be determined by the FDA and not in a private action. Solvay, on the

other hand, had "disclaimed any FDA related allegation." Relying on *Grove Fresh I,* the court explained that Solvay was permitted to use FDA regulations' definitions of "bioequivalence, pharmaceutical equivalence, and therapeutic equivalence" to establish the standard by which allegations of literal falsity are to be evaluated. The court opined that " 'false statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA,' where the truth or falsity of the statements in question can be resolved through reference to standards other than those of the FDA."The court cited *Mylan Labs v. Matkari* as support, noting that "[w]hether the tests cited by Matkari were falsified, unreliable, or non-existent and thus insufficient to support a claim of 'bioequivalence' was a factual issue properly considered by the court."The court distinguished *Ethex v. First Horizon* because Solvay was "not relying on either explicit or implicit FDA endorsement or terms that only the FDA can define."Instead, "[s]imilar to the plaintiff in *Grove Fresh,* Solvay may use the FDA regulations listing definitions of bioequivalence, pharmaceutical equivalence, and therapeutic equivalence to establish the appropriate standard by which to judge the literal falsity of Ethex's advertisements."The court also cited to *Grove Fresh'* s statement that the plaintiff could attempt to establish a violation of section 43(a) by providing other evidence of the proper market definition of generic, equivalent, comparable, or substitutable, and stated, "As Ethex acknowledges, and FDA determination is not necessarily required in order for two drugs to be properly considered equivalent."The court thus denied the 12(b)(6) motion because the claim did "not require the Court to determine anything within the particular jurisdiction of the FDA."

> FN10.*Solvay I* and *Solvay II* involved similar allegations, but were brought against two different defendants. Both cases were brought in the District of Minnesota, but were decided by two different Judges in the District.

***13** In *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.,* 388 F.Supp.2d 967 (E.D.Wis.2005), the court considered cross-motions for summary judgment in a case involving a prescription drug used for gastrointestinal and urological disorders, Nulev, and a "knock-off' competitor, Neosol. Plaintiffs alleged that, in commercial advertising, the defendant described Neosol and described Nulev as the "reference" product. *Id.* at 971.In considering whether the Lanham Act claim was precluded, the court noted that "the mere FDA regulation of a term dos not necessarily bar all Lanham Act claims that pertain to that term." *Id.* at 974.The court noted that the defendant "has failed to identify any section of the FDCA or its accompanying regulations that the court would be required to interpret or apply." *Id.* at 975.Neither Nulev or Neosol were listed in the Orange Book and there was "no record of the FDA evaluating the two products for pharmaceutical equivalence."Thus, "[i]n the absence of any FDA ruling or ongoing investigation, there is little chance that the court will usurp the role of the FDA."*Id.* The court noted that the defendant conceded that the claims did not run afoul of the FDA's jurisdiction "if Schwarz limits itself to the truth or falsity of the statements made in advertising" and "[t] o hold to the contrary would mean that an administrative scheme could eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction."*Id.* Thus, the court allowed Schwarz "to proceed on all remaining claims to the extent that it is not seeking the interpretation or direct application of any FDA regulation."*Id.* (citing *Grove Fresh I*).

In *Pediamed Pharmaceuticals, Inc. v. Breckenridge Pharmaceutical, Inc.,* 419 F.Supp.2d 715 (D.Md.2006), plaintiff complained that defendant marketed its product, V-Tann by noting, "Compare the active ingredients in Viravan-S," which was plaintiff's product. Plaintiff asserted that V-Tann had more phenylephrinetannate and pyrilaminetannate than Viravan and the two products had different specification ranges, and thus the products were not pharmaceutically equivalent. Plaintiff also com-

plained that defendant did not perform any tests to determine bioequivalence before launching V-Tann. The court surveyed the applicable case law:

> ...*Mylan* involved drugs for which the FDA had made a determination of equivalency, and thus the FDA's jurisdiction was clear. This case involves a class of drugs that is not required to file a new drug application or an ANDA, and the FDA typically does not make a equivalency determination for these drugs. Other courts have considered preclusion challenges in claims involving non-Orange Book drugs (i.e. where the FDA does not determine equivalency), and have drawn a line between claims that involve application and interpretation of the FDCA and its implementing regulations, and claims that do not. *See Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.,* 388 F.Supp.2d 967, 975 (E.D.Wis.2005) (allowing the plaintiff's complaint to proceed "to the extent that it is not seeking the interpretation or direct application of any FDA regulation"); *Solvay Pharms., Inc. v. Global Pharms.,* 298 F.Supp.2d 880, 884 (D.Minn.2004) (allowing the plaintiff's claims to proceed and noting that "FDA approval is not required in order to substitute the products or to make a determination of bioequivalence or therapeutic equivalence"); *Ethex Corp. v. First Horizon Pharm. Corp.,* 228 F.Supp.2d 1048, 1055 (E.D.Mo.2002) (allowing the plaintiff's claims to proceed to the extent that the claims did not rely on the FDCA); *Stratus,* 273 F.Supp.2d at 793 (stating that "issues that require direct application or interpretation of the FDCA or its implementing regulations or FDA policies should not be addressed by the Court" but "other issues are able to be resolved without the direct application or interpretation of the FDCA, implementing regulations or FDA policies"); *Healthpoint, Ltd. v. Ethex Corp.,* 273 F.Supp.2d 817, 845 (W.D.Tex.2001) ("There is a distinction between respecting the FDA's primary jurisdiction to determine in the first instance whether a drug is lawful,
> 'generic,' 'bioequivalent,' 'therapeutically equivalent,' or 'pharmaceutically equivalent' and, on the other hand, a Lanham Act claim that a false statement has been made about a product.").
>
> ***14** When the advertising at issue directly or indirectly implied that one non-Orange Book drug was the generic of or equivalent to another drug, courts have split over whether a claim was precluded. *See First Horizon,* 228 F.Supp.2d at 1055 (stating that this issue "is better left to the FDA" because "this Court would be forced to determine FDA policy in order to determine the truth or falsity of the 'generic' nomenclature"); *Ethex,* 273 F.Supp.2d at 846 n. 140 (finding the generic claim was within the FDA's jurisdiction); *Stratus,* 273 F.Supp.2d at 793 n. 147 (same); *but see Schwarz,* 388 F.Supp.2d at 975 (allowing the plaintiff's claim to proceed where the defendant used the term "reference" in comparing its drug to the plaintiff's drug); *Solvay,* 298 F.Supp.2d at 885 (allowing "generic" claims to proceed).

Id. at 724-25 (footnote omitted). The court then agreed "with the analysis in Schwarz and Solvay, which found that express or implied claims of generic or pharmaceutical equivalence were not precluded where the drug was not listed in the Orange Book and there was no indication that FDA approval is needed to make a claim of equivalency."*Id.* at 725.It continued,

> In the present case, both Viravan and V-Tann appear to be in the class of drugs that is not required to file a new drug application or an ANDA and as a result, neither drug is listed in the Orange Book. There is no evidence that the FDA has made a determination as to whether V-Tann is a generic or therapeutic equivalent to Viravan, or that it is planning to do so. Defendants do not argue that the FDA typically makes an equivalency determination of the class of drugs not listed in the Orange Book. Moreover, Defendants have not pointed specifically to any portion of the FDCA or to any implementing regulations to support

their assertion that Plaintiff's claims are based on the FDCA or its regulations, and therefore are precluded.

Id. at 726.

In *Midlothian Laboratories, L.L.C. v. Pamlab, L.L.C.,* 509 F.Supp.2d 1065 (M.D.Ala.2007), the court concluded that "[c]ourts have held that a false-advertising claim based on a representation of product equivalency-marketing a product as a 'generic' version of a branded product-may be maintained when 'the truth or falsity of the statements in question can be resolved through reference to standards other than those of the FDA,' but not 'where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA." *Id.* at 1085 (citing *Solvay,* 2004 WL 742033 at *3). The court noted that, in *Solvay,* the court denied a motion to dismiss, "finding that the plaintiff could prove under the Lanham Act that the defendant's drug product was not substitutable, and that any advertising of the defendant's drug as 'generic' could therefore be proven literally false." *Id.* at 1086.The court noted that the plaintiff supported its claim by asserting that defendant's product was not listed as therapeutically equivalent in the Orange Book, but that this was irrelevant because the products were undisputably not subject to the FDA-regulated drug-approval processes, and thus "any false-equivalency claim based on the fact that Midlothian's product does not appear in the Orange Book is preempted by the FDA's exclusive authority to approve products pursuant to the FDA." *Id* . "The simple fact that [defendant's] product does not appear in the Orange Book cannot support a valid claim of false equivalency under the Lanham Act." *Id.* The court then noted that the plaintiff asserted that the defendant's "representation of generic equivalence, in the absence of therapeutic equivalence testing, is literally false, and misleads pharmacists into believing that [defendant's] product is therapeutically equivalent to [plaintiff's] ." *Id.* However, the court stated, this "begs the question of whether therapeutic equivalence, as defined by the FDCA, is the standard by which legitimate generic substitution of medical food products must be judged." *Id.* The court then stated, "This articulation of the claim makes reference to standards of generic equivalence that only the FDA can define, but it does not require interpretation of those standards." *Id.* at 1086-87."A plaintiff 'may use the FDA regulations listing definitions of bioequivalence, pharmaceutical equivalence, and therapeutic equivalence to establish the appropriate standard by which to judge the literal falsity of [defendant's] advertisements." *Id.* at 1087 (quoting *Solvay,* 2004 WL 742033 at *4). Thus, the court concluded, the plaintiff's "claim that [defendant's] assertion of 'generic equivalence' is false advertising is not preempted by the FDA to the extent that [plaintiff] seeks to prove its claim with evidence that pharmacists understand 'generic equivalence' to imply therapeutic equivalence (or some other standard of equivalence), rather than with evidence that FDA regulations require therapeutic equivalence (a matter that only the FDA can decide)." *Id.* at 1087.

***15** In *Axcan Scandipharm, Inc. v. Ethex Corporation,* No. 07-2556, 2007 WL 3095367 (D.Minn. Oct.19, 2007), the court considered Ethex's argument that "by challenging their marketing of Pangestyme and Lipram as 'generic equivalents to' or 'substitutes for' Ultrase, Axcan has necessarily asserted that the Defendants are improperly representing their drugs as 'equivalent' to Ultrase*in the FDA's sense of that term*-in other words, the Defendants understand Axcan's claims to mean that the Defendants are improperly suggesting that Pangestyme and Lipram are pharmaceutically equivalent and bioequivalent to Ultrase" and that "whether their drugs are 'equivalent' to Ultrase in such fashions can only be determined by the FDA."The Court concluded, however, that the defendants "misapprehend the nature of Axcan's claims."It stated that "Axcan does not allege that the Defendants have falsely implied that their drugs are 'equivalent' in the FDA-sensethat is, bioequivalent and pharmaceutically equivalent to Ultrase.

Rather, Axcan asserts that, by advertising their drugs as 'generic equivalents to' or 'substitutes for' Ultrase, the Defendants have engaged in false advertising based on 'the proper market definition[s]' of these terms.""Stated differently, Axcan seeks to proffer evidence of the *generally understood meanings* of the terms 'generic equivalence' and 'substitute,' and not the FDA's definition of 'equivalence,' in order to establish the falsity of the Defendants' advertisements. Such claims in no way infringe on the FDA's right to determine whether two drugs are 'equivalent.' " The court further stated, however, that "[t]his is not to say that Axcan cannot use the FDA's definitions of bioequivalence or pharmaceutical equivalence when seeking to prove its claims. The FDA's 'primary jurisdiction' does not prohibit a plaintiff from relying on the FDA's definitions 'merely to establish the standard [that the] defendants allegedly failed to meet."The Court reasoned that "the issue here is not whether the FDA should deem the Defendants' products to be 'generic' versions of Ultrase; rather, the issue is whether, by advertising and marketing those products as 'generic equivalents to' or 'substitutes for' Ultrase when they do not contain the same ingredients, the Defendants' advertising is literally or implicitly false, based on common understood meanings of 'equivalent' and 'substitute.' " Further, plaintiffs' claims could be maintained "without infringing on the FDA's right to determine whether the Defendant's drugs are 'generic' versions of Ultrase under its own definition of 'equivalence.' "

Defendant Allan argues that Plaintiffs' claims are within the exclusive jurisdiction of the FDA because the claims are "for a violation of the Food Drug & Cosmetic Act."Defendants argue that "[t]here is no doubt that [plaintiffs'] allegations require that the Court infringe on the FDA's exclusive jurisdiction to determine whether AllanDerm-T is in fact a generic equivalent of Xenaderm" and "[a]ll of the Plaintiffs' specific complaints about false impressions or misleading advertising rest on the notion that AllanDerm-T may not satisfy the FDA's definition of a generic or equivalent drug."Defendants further contend that "to prove their case, [Plaintiffs] will have to conduct [bioequivalence and therapeutic equivalence] tests and then ask this Court to assume the precise role of the FDA in determining what the tests prove."In other words, Defendants contend, Plaintiffs can only win if the products are not equivalent, and only the FDA can make that determination. With regard to the common-law claims, Defendants argue that "[t]he only agency with authority to perform the tests and make the determination of generic equivalence is the FDA" and "[b]ecause a 'crucial element' of the claim requires application of the FDCA, it must be dismissed."

***16** In response, Healthpoint asserts that it "does not allege that Defendants have violated any provision of the FDCA" and that "Defendants would be liable for false advertising even if there were no FDCA governing the pharmaceutical industry."Instead, Plaintiffs argue, "this case is based on the false and misleading claims of generic equivalence and substitutability Defendants have made when advertising Allan Derm" and courts "have routinely held that such claims are actionable under the Lanham Act""even if the truth of those facts underlying them 'may be generally within the purview of the FDA.'" Thus, Plaintiffs argue, "courts are free to determine the truth or falsity of [defendants'] advertising and may rely on FDA definitions of equivalence to do so." Further, Plaintiffs contend that "Defendants are not free to state or imply that AllanDerm is equivalent to or substitutable for XenaDerm without proper factual support, or to make other false or misleading statements simply because a federal agency regulates drugs. To hold otherwise would mean that an administrative scheme could eviscerate a Lanham Act or related common claim over which the FDA has no jurisdiction."

There is no indication from the Complaint that the FDA has or intends to determine whether AllanDerm is a "generic" to or "substitute" for XenaDerm, or even whether they are pharmaceutically

equivalent, therapeutically equivalent, or bioequivalent. Plaintiffs do not claim that Defendants have violated an FDA regulation or FDCA provision. As is evident from the discussion of the applicable precedents, the majority of courts considering this issue in such a context have permitted the Lanham Act claim to proceed. *See Axcan, Midlothian, Pediamed, Schwarz Pharma, Solvay I, Solvay II, Sratus, Ethex.*The Court agrees with these decisions, and concludes that Plaintiffs' Lanham Act claims and other dependent claims should be allowed to proceed at this time.

Even among those courts allowing the claims to proceed, however, there is disagreement over whether Plaintiffs can or must use the FDA's definitions of related terms as the applicable standard in evaluating the truth or falsity of the advertising. *Compare Axcan Scandipharm,* 2007 WL 3095367 (plaintiff's claim could proceed if it used the "proper market definition" or "generally understood meaning") *with Solvay II,* 2004 WL 742033 (claim could proceed using FDA regulations or other market definition) *and with Stratus,* 283 F.Supp.2d 769 (plaintiff must use the FDA's definitions). In this case, it is not clear whether Plaintiffs seek to utilize the FDA regulations to establish the standard or whether they seek to utilize a market definition or definitions under Texas law.[FN11]Even were they to utilize solely the FDA regulations, it is not clear that this court would have to interpret these regulations in determining the merits of Plaintiffs' claims. Thus, the Court again finds that dismissal is not warranted at this time.[FN12]

FN11.*See*TEX. OCCUPATIONS CODE § 562.001 (defining generically equivalent, therapeutically equivalent, and pharmaceutically equivalent).

FN12. The Court notes, however, that the precedents appear to draw some fine distinctions between allowable and non-allowable claims, and the Court agrees with Judge Garcia that the distinction may be "blurry at times." The Court believes that it would therefore be appropriate to revisit this issue once the contours of Plaintiffs' claims are more developed.

C. Joint Motion for Status Conference and to Amend the Scheduling Order

***17** The parties have moved for a joint status conference, noting that this motion and others are pending before the Court. The Court will grant the motion and will issue an order setting a status conference by separate order. At the status conference, the Court will consider the parties' positions regarding amending the scheduling order, including the trial date, as well as Defendants' Motion for Leave to File Amended Answer and Counterclaim (docket no. 33) and Plaintiffs' Response in Opposition (docket no. 37).

Conclusion

For the reasons stated above, the Court DENIES Defendant's Motion to Dismiss (Docket No. 11) and GRANTS the parties' Joint Motion for a Status Conference (docket no. 44). The Court will issue a separate order setting the status conference.

It is so ORDERED.

W.D.Tex.,2008.
Healthpoint, Ltd. v. Allen Pharmaceutical, LLC
Slip Copy, 2008 WL 728333 (W.D.Tex.)

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Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2007 WL 704511 (D.Ariz.)
(Cite as: 2007 WL 704511 (D.Ariz.))

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Only the Westlaw citation is currently available.

United States District Court, D. Arizona.

SOILWORKS, LLC, an Arizona Limited Liability Company, Plaintiff,

v.

MIDWEST INDUSTRIAL SUPPLY, INC., an Ohio corporation authorized to do business in Arizona, Defendant.

No. 06-2141-PHX-DGC.

March 5, 2007.

E. Scott Dosek, Kutak Rock LLP, Scottsdale, AZ, John Patrick Passarelli, Kutak Rock LLP, Omaha, NE, for Plaintiff.

George Chun Chen, Lawrence Gd Scarborough, Bryan Cave LLP, Phoenix, AZ, for Defendant.

ORDER

DAVID G. CAMPBELL, United States District Judge.

***1** Pending before the Court is Defendant Midwest Industrial Supply, Inc.'s motion to dismiss all claims asserted by Plaintiff Soilworks, LLC. Dkt. # 8. For the reasons stated below, the Court will deny Defendant's motion.[FN1]

> FN1. The request for oral argument is denied because the parties have thoroughly discussed the law and evidence and oral argument will not aid the Court's decisional process. *See Mahon v. Credit Bur. of Placer County, Inc.,* 171 F.3d 1197, 1200 (9th Cir.1999).

I. Factual Background.

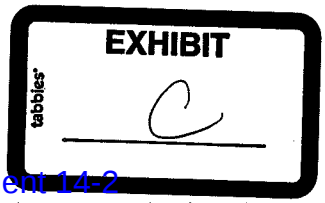
Plaintiff distributes environmentally-safe dust and erosion control agents throughout the United States, including a dust control product named Durasoil. Dkt. # 11 at 2-3. Defendant also provides dust and erosion control products, for several of which it recently was issued U.S. Patents numbered 7,074,266 and 7,081,270. Dkt. # 8 at 3. Upon receipt of these patents, Defendant sent Plaintiff two letters informing it of the patents, expressing concern that Durasoil infringes the patents, and seeking more information about Durasoil upon which to base a decision of infringement or non-infringement. *Id.* at 4-6.Defendant also sent a letter to one of Plaintiff's customers, Polar Supply Company, Inc., regarding the patents, Plaintiff's possible infringement, and Defendant's ability to pursue anyone who makes, sells, or uses an infringing product. Dkt. # 11, Ex. 1. Finally, Defendant published marketing materials describing its new patents, its ability to pursue infringers, and Plaintiff's position as an imitator of Defendant's products. *Id.,* Ex. 4.

In response, Plaintiff filed a complaint on September 7, 2006 seeking an injunction and damages under the Declaratory Judgment Act, the Lanham Act, and state law. Dkt. # 1. Plaintiff seeks a declaration that it is not infringing Defendant's patents and an end to Defendant's accusations of infringement.*Id.* at 4-6.Defendant moves to dismiss all counts for lack of jurisdiction and failure to state a claim upon which relief can be granted. Dkt. # 8.

II. Count II: Declaratory Judgment.

A. Legal Standard

The Declaratory Judgment Act authorizes the Court to "declare the rights and other legal relations of any interested party seeking such declaration" when there is an "actual controversy." 28 U. S .C. § 2201(a). In patent cases, declaratory judgment is usually sought by a party who, rather than waiting to be sued for patent infringement, seeks a legally binding affirmation that it is not infringing on another party's patent. *BP Chems. Ltd. v. Union Carbide Corp.,* 4 F.3d 975 (Fed.Cir.1993). Federal Circuit law controls such actions. *Shell Oil Co. v.*



Amoco Corp., 970 F.2d 885, 888 (Fed.Cir.1984); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed.Cir.1987).

"Whether an actual controversy exists is a question of law" for the Court to decide. *Dainippon Screen Mfg. Co. v. CFMT, Inc.*, 142 F.3d 1266, 1273 (Fed.Cir.1998). The Federal Circuit has developed a two-part test to guide the Court's analysis:

> There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

***2** *Sierra Applied Sciences, Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1373 (Fed.Cir.2004); *see Societe de Conditionnement en Aluminum v. Hunter Eng'g Co.*, 655 F.2d 938, 944 (9th Cir.1981)."The first prong looks to the patentholder's conduct, and the second prong looks to the potential infringer's conduct. The burden is on the ... plaintiff 'to establish that jurisdiction over its declaratory judgment action existed at, and has continued since, the time the complaint was filed.' " *Sierra Applied Sciences,* 363 F.3d at 1373 (citations omitted).

"Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction" if doing so would better serve the policy behind the Declaratory Judgment Act, which is to afford relief from uncertainty with respect to rights, status, and other legal relations. *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed.Cir.1996) (citing *Public Serv. Comm'n v. Wycoff, Co.*, 344 U.S. 237, 241 (1952)).

B. Analysis.

Defendant's accusations of infringement satisfy the first prong of the Federal Circuit test. "If the defendant has expressly charged a current activity of the plaintiff as an infringement," reasonable apprehension is established. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed.Cir.1988). Defendant's letters to Plaintiff appear to have been carefully drafted to avoid a direct accusation of infringement, but Defendant's letter to Polar Supply Company was more direct, setting forth Defendant's claimed rights under the patents and then referring to Plaintiff as "someone ... accused of infringement." Dkt. # 11, Ex. 1.

Plaintiff's marketing and selling of its Durasoil product, in light of Defendant's letter regarding possible infringement by that product, satisfies the second prong of the Federal Circuit test. Neither party appears to dispute that Plaintiff's present activity could constitute infringement.

Defendant argues that the instant claim is premature and that allowing it to proceed would discourage patent holders from communicating with potential infringers. Dkt. # 8 at 16. Communications can occur, however, without accusations. Defendant elected to accuse Plaintiff of patent infringement in the communications with Plaintiff's customer, Polar Supply. Such accusations create an actual controversy and enable the accused infringer to seek relief under the Declaratory Judgment Act. The Court finds that retaining jurisdiction would best serve the purpose of the Act.[FN2]

> FN2. Defendant may divest the court of jurisdiction over this claim by covenanting not to sue Plaintiff or its customers for infringement. *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed.Cir.1995).

III. Count I: False Representation under Lanham Act, § 43(A).

A. Legal Standard for Dismissal Under Rule 12(b)(6).

A district court may not dismiss a complaint for

failure to state a claim "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claims which would entitle him to relief." *Barnett v. Centoni,* 31 F.3d 813, 816 (9th Cir.1994). When analyzing a complaint for failure to state a claim, "[a]ll allegations of material fact are taken as true and construed in the light most favorable to the non-moving party." *Smith v. Jackson,* 84 F.3d 1213, 1217 (9th Cir.1996). In addition, the Court must assume that all general allegations "embrace whatever specific facts might be necessary to support them." *Peloza v. Capistrano Unified Sch. Dist.,* 37 F.3d 517, 521 (9th Cir.1994). Defendant has provided no controlling authority to support its argument that claims under the Lanham Act require the heightened pleading of Rule 9(b). The Court accordingly will apply traditional pleading standards.

B. Analysis.

***3** To state a claim for false advertising under the Lanham Act, a plaintiff must allege the following:

> 1) defendant made false or misleading statements about his own [or another's] product; 2) those advertisements actually deceived or have the tendency to deceive a substantial segment of their audience; 3) such deception is material, in that it is likely to influence the purchasing decision; 4) ... falsely advertised goods [were caused] to enter interstate commerce; and 5) plaintiff has been or is likely to be injured as the result of the foregoing either by direct diversion of sales form itself to defendant, or by lessening of the good will which its products enjoy with the buying public.

Cook, Perkiss and Leihe, Inc. v. Northern California Collection Service Inc., 911 F.2d 242, 244 (9th Cir.1990). The Court has reviewed Plaintiff's complaint and finds that it sufficiently pleads each of these elements.

Citing *Zenith Electronics Corp. v. Exzec, Inc.,* 182 F.3d 1340, 1354 (Fed.Cir.1999), Defendant argues that the complaint must be dismissed because it fails to plead bad faith. *Zenith* establishes a bad faith requirement when the Lanham Act claim arises from "marketplace statements regarding patent infringement" and patent scope. *Id.* Count I of Plaintiff's complaint, however, does not mention patent infringement allegations. Dkt. # 1 at 4. Moreover, *Zenith* is a decision of the Federal Circuit and Ninth Circuit law controls this Lanham Act claim. *See*28 U.S.C. § 1295.

IV. Count III: Misappropriation of Goodwill.

Defendant argues that misappropriation of goodwill is only a claim under Lanham Act § 43(a), and that because Plaintiff neither specified that it brings the claim under the Lanham Act nor adequately pled a claim under the Lanham Act, Count III should be dismissed. In response, Plaintiff clarifies that it does indeed bring the misappropriation of goodwill claim under the Lanham Act. Rather than dismissing the count with leave to amend, the Court will construe the misappropriation of goodwill claim as part of Plaintiff's § 43(a) claim.

V. Counts IV and VI: State Law Claims.

Plaintiff alleges state law claims of tortious interference and unfair competition. Dkt. # 1 at 5-6. These claims are closely related to the federal law claims and form part of the same controversy. The Court will exercise supplemental jurisdiction over the state law claims in the interest of efficiency. *See*28 U.S.C. § 1367.

IT IS ORDERED that Defendant's motion to dismiss all claims (Dkt.# 8) is denied.

D.Ariz.,2007.
Soilworks, LLC, v. Midwest Industrial Supply, Inc.
Not Reported in F.Supp.2d, 2007 WL 704511 (D.Ariz.)

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